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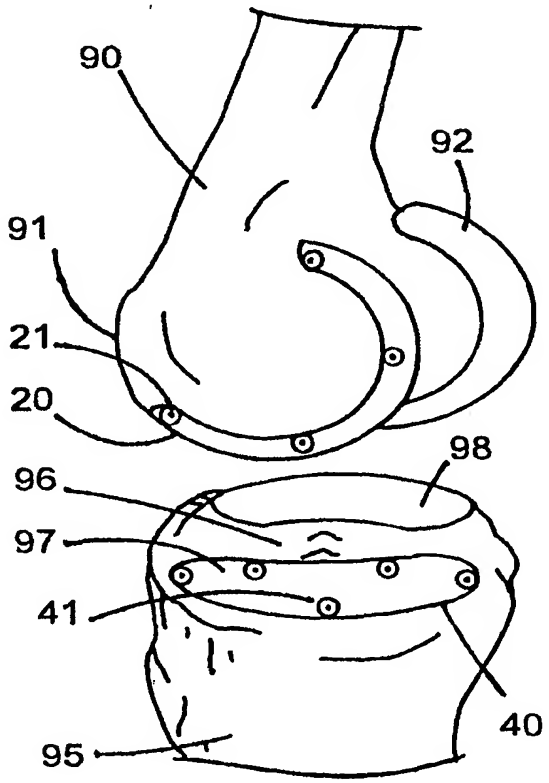
(54) Title: ARTHROSCOPIC REPLACEMENT OF CARTILAGE USING FLEXIBLE INFLATABLE ENVELOPES

(57) Abstract

A flexible "scaffold envelope" (20, 40) can be used to replace damaged cartilage in knees, hips, shoulders, or other joints of a mammalian body. Designed for arthroscopic use, the envelope is flexible, so it can be rolled or folded, and inserted into a knee or other joint via a small incision. Before insertion, a segment of damaged cartilage is removed from a bone surface. The bone is prepared using various tools, and alignment guides disclosed herein. After the envelope is inserted into the joint, the scaffold envelope is unfolded, positioned, anchored, and cemented to the bone surface. The envelope is then filled, via an inlet tube, with a polymeric substance that will set and solidify at body temperature. Using these materials and methods a synthetic non–resorbable cartilage replacement is created, having a smooth surface, and non–rigid stiffness closely resembling natural cartilage.



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ARTHROSCOPIC REPLACEMENT OF CARTILAGE USING FLEXIBLE INFLATABLE ENVELOPES

BACKGROUND OF THE INVENTION

This invention is in the field of surgery, and more particularly, arthroscopic surgery on joints such as knees, shoulders, or hips. It relates to using arthroscopic devices and methods to replace damaged or diseased cartilage surfaces in mammalian patients.

Cartilage is the type of tissue that coats the ends (or other friction-bearing sites) of various types of bones. It is reasonably hard but not rigid. The cartilage surfaces on two interacting bones in a joint "articulate" against each other (i.e., the two cartilage surfaces slide across each other, while they press against each other, aided and lubricated by synovial fluid in the joint).

Because of physiological factors, the joints that most frequently need repair or replacement of damaged cartilage are knee joints, hip joints, and shoulder joints. To describe and illustrate this invention, the discussion below focuses mainly on knee joints. However, as discussed below, the methods and devices disclosed herein also can be adapted for use in repairing shoulder and hip joints. If desired, the methods and devices of this invention also can be adapted for use in replacing damaged or diseased cartilage segments in other joints as well, such as finger joints, ankles, etc.

The initial discussion below focuses on a femoral-tibial compartment, i.e., the main load-bearing surfaces between the femur (the thighbone) and the tibia (the shinbone). After that description, various enhancements to this invention are described and illustrated in a patello-femoral interface, since it is easier, in some respects, to illustrate that simpler part of the knee. It should be recognized that the various positioning, anchoring, and other enhancements that are described and illustrated with respect to the patella (the kneecap) can also be used in replacing a cartilage segment in a femoral-tibial compartment, and can also

be adapted for use in replacing damaged or diseased cartilage in hip or shoulder joints as well.

Various "classical" techniques, tools, and implanted devices that have been used for many years to repair damaged cartilage in knee joints are discussed in medical texts such as *Campbell's Operative Orthopedics*, a five-volume treatise. Surgical tools and implantable devices for repairing knee joints can generally be classified into two categories (although, as noted below, these categories have begun to overlap substantially in recent years). The first category, often referred to as "open knee" surgery, requires that the knee must be cut open, to expose at least a portion of the bones that are being worked on, giving the surgeon direct access to the areas being worked on. "Open knee" surgery is used in various situations, including: (1) patellar implants, in which a device is inserted to assist a damaged patella (kneecap), as described in 3,927,423 (Swanson 1975); and, (2) cases that require what surgeons call a "knee replacement" or "total knee replacement" (abbreviated as TKR), in which the ends of the tibia (shinbone) and/or the femur (thighbone) are either cut off or otherwise cut, grinded, or machined to prepare an exposed bone surface, followed by permanently implanting one or more devices on the exposed bone surfaces. Currently, the only TKR devices that have been approved for use in the United States use a metal-surfaced femoral component and a plastic-surfaced tibial component. However, other interfaces have been developed for other joints (including metal-on-metal devices for use in the hip), and research is being done on ceramic replacement joints. Additional patents in the area of "open knee" surgery include US patents 5,171,244 (Caspari et al 1992) and 5,358,525 (Fox et al 1994).

The second major type of approach to repairing knees and other joints is generally referred to as "arthroscopic" surgery. This approach is sometimes called "minimally invasive surgery," but that term is broader and not precise. "Arthroscopic" surgery involves cutting two or more small holes through the patient's skin, near the area to be worked on. A slender light source (usually a flexible fiber optic cable) coupled to a miniaturized lens for a video-type camera are inserted through one hole, so the surgeon can see what he (or she) is doing beneath the skin. One or more tissue manipulating instruments (such as a scalpel blade, a scissors-type cutting device with one or two movable blades, a gripping device such as forceps or a clamp, etc.) are inserted through a second and possibly additional holes. Patents that disclose instruments or devices used in arthroscopic knee repair or other types of similar surgery (such as laparoscopic surgery) include US patents

4,203,444 (Bonnell 1980), 4,983,179 (Sjostrom 1991), 5,304,181 (Caspari et al 1994), and 5,322,505 (Krause et al, 1994), and numerous other patents as well.

In recent years, the boundary between open-knee and minimally-invasive knee surgery have become blurred. For example, various patents issued to Caspari et al (including US patents 5,171,244; 5,263,498; 5,336,266; and 5,395,376) relate to steel-type devices that may be several inches wide or long, which are inserted into the knee through incisions that may also be several inches long. Although this is not truly arthroscopic surgery, it can be called "minimally invasive" surgery, since any incisions that are made through the skin are kept to a minimum size, in view of the needs of the surgery. Accordingly, "minimally invasive surgery" is regarded herein as a broader and less precise term, which includes both arthroscopic surgery, as defined above, and various other types of surgery in which any incisions through the skin are kept as small as possible. "Minimally invasive surgery" clearly excludes so-called "total knee replacement"; however, nearly any other type of skillful surgery on a knee might be regarded as "minimally invasive", under the broadest implications of the term.

Non-Relevant Meniscus and Cell Implant Art

The current invention relates to implantable devices that are securely anchored to a bone surface. As such, this invention does not relate to items of prior art involving surgical implantation of a "meniscus", which is a peripherally-anchored device that is sometimes implanted in a damaged knee to provide a cushion between the femur and tibia bones. Meniscus implants are disclosed in patents such as US 4,344,193 (Kenny 1982) and 5,344,459 (Swartz 1994). Such implants are not relevant herein, since this invention relates solely to implanted cartilage-replacement devices that are permanently and securely anchored to a bone surface.

Extensive prior art also exists on efforts to surgical transplantation of chondrocyte or other cells that can generate and secrete new cartilage. Articles describing such efforts include Brittberg et al 1994, Chen et al 1997, Minas et al 1997, and Thornhill 1997; US patents include 4,919,667 (Richmond 1990), 5,306,311 (Stone et al 1994), 4,846,835 (Grande 1989), 5,041,138 (Vacanti et al 1991), 5,206,023 (Hunziker 1993), 5,769,899 (Schwartz et al 1998), and numerous others. However, the current invention is entirely different and distinct from such efforts. This invention involves synthetic, non-resorbable devices that are intended to replace, rather than regenerate, damaged cartilage.

It should be recognized that repair methods involving transplanted chondrocyte cells require long recovery times. Typically, a patient receiving a chondrocyte cell transplant in a knee joint is prohibited from putting any weight on the knee for at least 6 weeks, and many patients are told to not put any weight on the knee for even longer periods, such as 12 weeks. Even after a patient can begin using the knee again, full recovery from chondrocyte cell transplant surgery typically requires many months. This type of slow, prolonged recovery greatly increases the total costs of treatment and recovery (including, in many cases, lost work and lost wages), and it tends to limit candidate patients to relatively young people who were injured in a sporting event, auto accident, etc. Elderly patients, who are not as active and who will not have to live with a serious knee problem for another 40 years or more, are usually advised to get "total knee replacement" surgery instead.

It should also be noted that under the current technology, cell transplant methods are severely limited in their ability to repair large defects in cartilage. The maximum size limit for successful cell transplant efforts is generally regarded as being in the 1 cm^2 range; efforts to regenerate larger areas of cartilage, using cell implant techniques, have low success rates.

By contrast, the current invention offers a method of surgically replacing a large segment of cartilage (including entire cartilage segments in knee, hip, or shoulder joints), using arthroscopic techniques. By using a completely mechanical device involving an injectable synthetic polymer that can set and harden within a matter of minutes, and by using arthroscopic tools and methods to minimize surgical damage to the surrounding skin, muscle, ligaments, and blood vessels, this invention will minimize the patient's recovery period. A patient who receives this type of treatment usually will be able to place at least some weight on the repaired joint within a day or two after the surgery, and typically will need only a cane for a week or so after the surgery, rather than needing crutches or a wheelchair for weeks or months.

Implantable or Injectable Polymers

Several US patents disclose various types of polymers or proteins that, assertedly, can be injected into a joint as a liquid or semi-liquid composition that subsequently harden into a solidified material.

For example, US patent 5,556,429 (Felt 1996) discloses injection of a fluidized mixture of a biocompatible polymer (such as a silicone or polyurethane polymer) and a

biocompatible "hydrogel" (a hydrophilic polymer, formed by steps such as using an agent such as ethylene dimethacrylate to cross-link a monomer containing a hydroxyalkyl acrylate or methacrylate), into a joint such as the knee, after one or more bone surfaces have been properly prepared. After injection, the polymer and hydrogel mixture can be set into solidified form by means such as ultraviolet radiation, which can be introduced into the subcutaneous area by a fiber optic device. Felt's '429 patent asserts that after the polymer-hydrogel mixture has set, it can be finished and sculpted by means such as a retractable scalpel with an electrically heated tip to melt the surface of the polymeric material, thereby allowing it to be sculpted or otherwise modified by the spatula tip. After the heated tip is removed from the polymer surface, the melted surface material will cool again, and will solidify in its newly sculpted form.

That approach may offer promise, but it is not being used by surgeons, and it apparently suffers from several limitations and drawbacks. First, a surgeon's ability to ensure complete and thorough setting of a polymer-hydrogel mixture (especially those portions of the mixture that are directly next to a bone, and thus obscured from direct exposure to ultraviolet light) is limited and uncertain. Second, a surgeon has only limited ability to ensure that the polymerizing fluid, once it sets, becomes securely and permanently anchored to the bone surface.

Concerns over adhesion are highly important, for at least two reasons. Most notably, the presence of a hydrogel mixed with the polymer will detract from the adhesive strength of the final polymer. A hydrogel necessarily has a high water content, and the water in the gel cannot and will not adhere to the bone; in simple terms, a hydrogel is included in the mixture in order to make the final material slippery, rather than sticky. In addition, polymeric agents that have been selected for toughness, smoothness, and durability, but which also must provide a substantial amount of non-rigid, non-brittle cushioning in a manner comparable to cartilage, are not likely to also have the characteristics of an ideal adhesive.

Those important limitations, as well as various others, are addressed and overcome by the subject invention disclosed herein.

Additional prior art on surgically-implantable polymers is contained in numerous published items; recent review articles include Peppas et al 1994, Hubbell 1995, Stokes 1995, Burg et al 1997, Lewis 1997, Kim and Mooney 1998, and Ambrosio et al 1998. Other discussions of biocompatible implant materials are also available in various

textbooks, such as Silver 1994.

Prior to this invention, no one has successfully managed to create workable and satisfactory methods and devices for arthroscopically implanting a completely synthetic, permanent, non-resorbable device that can completely replace a large segment of damaged or diseased cartilage in a knee, hip, or shoulder joint. All prior efforts have suffered from important limitations and drawbacks, which have forced surgeons to use "open knee" and similar surgical methods that inflict extensive damage on the skin, muscles, ligaments, and blood vessels that surround and enclose the joint, whenever a large segment of cartilage must be replaced by a non-resorbable mechanical implant device.

Accordingly, one object of this invention is to disclose improved methods and devices for replacing damaged cartilage in a knee (or other joint) using arthroscopic methods, tools, and devices, in a way that eliminates the need for cutting open the joint to expose the cartilage segment that needs to be repaired.

Another object of this invention is to disclose a method of arthroscopic surgery on knees or other joints, which is capable of replacing an entire femoral condyle or tibial medial or lateral plateau with a hardened synthetic device, and which thereby overcomes and avoids the size limitations of cartilage regeneration attempts that can repair a cartilage defect only up to about 1 square centimeter in size.

Another object of this invention is to disclose a method of arthroscopic surgery on knees or other joints, in which a device is implanted inside the joint, wherein the device provides an immediate and substantial improvement in the condition and operability of the joint, without requiring a prolonged recovery period of weeks or months before weight-bearing loads can again be placed on the repaired joint.

Another object of this invention is to disclose a method of using a flexible "scaffold envelope" which, using arthroscopic surgical tools, can be inserted into a diseased or damaged joint such as a knee. After it has been properly positioned over a bone surface from which a damaged cartilage segment has been removed, the scaffold envelope is anchored permanently to the bone surface, then filled with a curable polymer. Because the scaffold envelope is inserted into the knee in a deflated and rolled-up configuration, it can be implanted using arthroscopic methods regardless of the size or surface area of the final implanted device.

Another object of this invention is to disclose methods and tools for properly preparing a bone surface to remove an entire segment of damaged cartilage, using

arthroscopic tools and methods, so that the bone surface will be ready to receive a flexible scaffold envelope as described herein. The methods and tools used during cartilage removal and bone preparation include various types of alignment templates and guides which remain outside the joint, and which are temporarily affixed to one or more bones (such as the femur and tibia bones) by means of transdermal pins that are placed in the bone(s) during surgery.

These and other objects of the invention will become more apparent through the following summary, drawings, and description of the preferred embodiments.

SUMMARY OF THE INVENTION

A flexible "scaffold envelope" can be used to replace damaged cartilage in knees, hips, shoulders, or other joints of a mammalian body. Designed for arthroscopic use, the envelope is flexible, so it can be rolled or folded and inserted into a knee or other joint via a small incision. Before insertion, a segment of damaged cartilage is removed from a bone surface, and the bone is prepared using various tools and alignment guides disclosed herein. After the envelope is inserted into the joint, it is unfolded, positioned, and anchored and cemented to the bone surface. The envelope is then filled, via an inlet tube, with a polymeric substance that will set and solifidy at body temperature. During filling and setting, the surgeon can manipulate the exterior shape of the scaffold envelope, to ensure that the implant will have a proper final shape after the polymer has cured into fully solidified form. Using these materials and methods, a synthetic non-resorbable cartilage replacement is created, having a smooth surface and a non-rigid stiffness closely resembling natural cartilage. Various devices and methods are disclosed to aid this procedure, including alignment guides and tools to ensure proper preparation of a large bone surface, and correct positioning, anchoring, and filling of the scaffold envelope.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 illustrates the arrangement of the femur (thighbone) and tibia (shinbone) in a knee, showing the two rounded parallel femoral condyles, and the two concave tibial plateaus, which are separated by the tibial spine. In a uni-compartmental repair, one femoral condyles has been covered by a femoral scaffold, and the corresponding tibial

plateau has been covered by a tibial scaffold.

FIGURE 2 is an oblique view showing a femoral scaffold envelope, designed to be placed on the convex surface of a single femoral condyle (medial or lateral). This envelope has a smooth-curved (rather than faceted) anchoring surface.

FIGURE 3 is a side view showing how a femoral scaffold envelope with a faceted anchoring surface will interact with a femoral condyle surface that has been prepared by a grinding operation to have complementary facets.

FIGURE 4 illustrates how a tibial plateau is prepared, by a grinding operation, to have a flat horizontal platform which will accommodate a tibial scaffold envelope with a flat anchoring membrane and a concave articulating membrane.

FIGURE 5 depicts a stabilizing platform that is affixed to the tibia bone via pins, and which is also coupled to the femur bone via cammed hinges, to ensure proper alignment of the femur and tibia at all stages of flexion and extension of the knee.

FIGURE 6 depicts a grinding burr mounted at the end of a shaft sleeve, for use in removing cartilage and preparing a bone surface for a scaffold implant. The grinding tool passes through an aligning and stabilizing guide that is temporarily affixed to the platform mounted on the tibia bone.

FIGURE 7 depicts a grinding burr mounted at a right angle with respect to the main shaft sleeve. This type of burr, in conjunction with stationary alignment clamp, can be used to prepare a smoothly curved surface on a femoral condyle.

FIGURE 8 depicts an alignment device which uses both a transverse femoral pin and a transverse tibial pin, with a cammed disk at each end of the femoral pin and a rigid strut positioned between the two pins, to emulate the natural cammed structure of a femoral condyle and ensure proper alignment of the femur and tibia at all stages of flexion and extension of the knee.

FIGURE 9 shows a slotted burr guide with a movable square sleeve, to prevent any angling of a grinding or other tool which passes through the sleeve.

FIGURE 10 shows a slotted burr guide that allows the burr head to be tilted upward, but only at two specific positions, to assist in preparing a flat tibial plateau that is provided with a groove at either or both of two fixed location, to accommodate a scaffold envelope with a "keel" structure as shown in Fig. 5.

FIGURE 11 depicts a "travelling guide" which moves in a constrained path while tightly holding a grinding tool. By varying the lengths and fixation points of the rotatable

struts which hold the travelling guide, this type of guide can be constrained to either a perfectly circular path, or an elliptical, cycloidal, or other cam-like path.

FIGURE 12 depicts a penetration guide with vertical supports having two curved slots, which will constrain and guide the motion of a tool with protruding lateral pins on both sides of the shaft sleeve.

FIGURE 13 depicts a surface-shaping guide that is inserted into a knee joint and held in position adjacent to a tibial scaffold while the scaffold is being filled.

FIGURE 14 is a cross-section of a patello-femoral joint, which illustrates, on both bone surfaces: (i) an implanted positioning ring which is anchored to a bone surface and which has an open center; and (ii) a scaffold envelope which is secured inside the positioning ring.

FIGURE 15 is a cross-section of patello-femoral implants, with the articulating surface of the patellar scaffold coated by a metallic layer, and wherein the femoral implant has a keel structure that extends downward and fits into a groove created in the bone surface, for greater strength and stability.

FIGURE 16 depicts a center guide pin inserted into a femoral head through the femoral neck, and a hollow drill bit which is being used to remove a core (dowel) of bone from the femur, to create a center access port for arthroscopic work on the cartilage surfaces on a femoral head and acetabular socket.

FIGURE 17 (which includes parts A, B, and C) depicts a collapsible grinding device, which can be retracted to its smallest diameter by rotating it in a counterclockwise direction, allowing it to be passed through a portal tube in that position. Once in position inside a hip or shoulder joint, the grinding head can be extended in an outward radial direction, by rotating it in a clockwise direction.

FIGURE 18 depicts a grinding operation to remove cartilage from a femoral head and/or acetabular socket, to prepare the underlying bone surfaces for implantation of synthetic inflatable envelopes. This drawing also depicts two flanking tubes which will provide additional access ports for removing cartilage and implanting a synthetic envelope.

FIGURE 19 depicts a collar device with tool guides mounted at the exposed ends of the two flanking ports. In conjunction with leveraging ring-pivots near the center of the tool shafts, these guides can help a surgeon control the position and motion of a tool tip deep inside a hip joint.

FIGURE 20 (which includes parts A and B) depicts a grinding tool that can be

passed through either flanking portal in a retracted position, and extended for an angled grinding operation once it is in position inside a hip joint.

FIGURE 21 (which includes parts A and B) depicts an arthroscopic tool with a "wiry brush" head, in both retracted and extended positions, for use in removing cartilage and debris from inside a hip or shoulder joint.

FIGURE 22 is a cross-sectional depiction of a repaired hip joint, with a first implant anchored to the acetabular socket, a second implant anchored to the femoral head and bone, and with a synthetic implant, bone dowel, or similar replacement filling the center access port.

FIGURE 23 depicts an acetabular socket with an implant having a horseshoe-shaped raised surface, which can be a metallic surface if desired, to mimic the shape of the natural cartilage surface in an acetabular socket.

FIGURE 24 depicts a tool guide mounted on two pins that have been driven into a humerus bone in an arm, showing two tool guide components coupled to a stabilizer platform, for replacing cartilage in a shoulder joint.

FIGURE 25 depicts a repaired shoulder joint, with a humeral implant have a keel structure that extends down into the main shaft of the humerus.

FIGURE 26 (which includes parts 26A through 26E) illustrates certain processes involving synovial fluids and cartilage membranes in a knee joint under relaxed, compressed, and articulating conditions.

FIGURE 27 depicts a multi-layer envelope having a semi-permeable outer membrane which interacts with synovial fluid components in a way that mimics the interactions of cartilage membranes and fluid components in a healthy knee.

FIGURE 28 depicts a sealed plastic envelope which maintains the sterility of a flexible scaffold envelope which has been rolled up and stuffed inside an arthroscopic insertion tube.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

For purposes of explanation and illustration, the initial discussion below focuses mainly on arthroscopic implantation of two inflatable scaffolding devices, to replace damaged cartilage segments on the load-bearing interface between a femur (thighbone) and tibia (shinbone). One scaffold will create a convex layer for a femoral condyle; the other

scaffold will create a concave layer for a tibial plateau.

Following that discussion, various options and enhancements are described and illustrated in a discussion of a patellar (kneecap) implant. Those options and enhancements are covered in the patellar analysis, because they are easier to illustrate in that context; however, they are also feasible in femoral and/or tibial implants.

As is well-known to surgeons who repair knees, and as shown in a simplified manner in Fig. 1, the lower end of femur 90 (in layman's terms, the "thighbone"), has two convex rounded segments, shown as structures 91 and 92 in Fig. 1. These are the two femoral condyles. The "medial" condyle 91 is on the inner side of the leg, while the "lateral" condyle 92 is on the outer side of the leg. These two femoral condyles are generally parallel to each other, in a configuration that is comparable to the two rims of a pulley.

The two femoral condyles in a knee joint interact with a complementary surface (called the tibial plateau) on the upper end of tibia 95 (the shinbone). Rather than being a simple concave surface, the tibial plateau has a raised promontory 96 in its center with two small peaks, called the "tibial spine". This tibial spine 96 helps create and define two concave surfaces, shown as bone surfaces 97 and 98 in Fig. 1, on both sides of the tibial spine 96. These two concave structures are the medial tibial plateau 97, on the inner side of the leg, and the lateral tibial plateau 98, on the outside of the leg. These are also referred to simply as the medial plateau, and the lateral plateau.

The structures and arrangement of the femoral and tibial surfaces helps stabilize the knee while permitting normal motion. When a knee is repeatedly bent and straightened, such as during walking or running, the two femoral condyles slide and roll back and forth in the medial and lateral tibial plateaus, on opposite sides of the tibial spine. When a person stands or engages in various other activities, this arrangement also gives the knee a substantial amount of rotational movement, allowing the person to move his feet slightly outward in a manner that offers better stability for standing and similar actions.

To simplify and clarify this analysis, the description below describes replacement of cartilage covering a single femoral condyle (either medial or lateral), and a single tibial plateau. After the implant procedure has been completed, the two scaffolds will press and slide against each other as "articulating" surfaces in the patient's knee. This type of repair, often referred to as "uni-compartmental" repair, is fairly common, since a damaged and irregular surface on either of two articulating surfaces often inflicts damage on the surface

it rubs against, inside the knee.

If necessary, both femoral condyles and/or both tibial plateaus in a single knee can be resurfaced using scaffold envelopes as disclosed herein, either in a single arthroscopic procedure, or in a series of two such procedures on different days. In one preferred embodiment, a "bi-compartmental" operation would simply repeat the steps described herein, on both the medial (inner) and lateral (outer) sides of a single knee, using two different scaffolds, each of which covers a single (medial or lateral, but not both) femoral condyle or tibial plateau.

In an alternate preferred embodiment, a substantially larger femoral scaffold can be used which will generally have a "U" or horseshoe shape, which can handle both the medial and lateral condyles with a single scaffold envelope. This type of envelope can be provided with separate compartments for the two condyles, if desired. In addition, a single device (with multiple compartments, if desired, can also cover the patellar-facing surface of the femur as well, by means of a scaffold extension which will extend in an upward direction, on the anterior surface of the femur, once it is anchored to that femoral surface.

Similarly, a U-shaped tibial plateau implant can also be used, which will cover both the medial and lateral components of a tibial plateau, and which will generally circumscribe the tibial spine, in the center, which is not covered by cartilage.

Alternately, depending on the condition of the cartilage surfaces in a knee, it may be necessary to resurface only a single femoral condyle, or a single tibial plateau; or, it may be necessary to resurface both femoral condyles (medial and lateral) without resurfacing the tibial plateaus, or vice-versa.

Accordingly, referring to the drawings, callout number 20 in Fig. 2 (and in various other figures) refers to a femoral scaffold envelope, designed to be placed on the convex surface of a single femoral condyle (medial or lateral). Callout number 40 in Fig. 1 refers to a tibial scaffold envelope, which will have a similar structure and function as a femoral scaffold 20, but with a somewhat different external shape.

Both of these inflatable scaffold envelopes (femoral scaffold 20 and tibial scaffold 40) are referred to interchangeably as scaffolds or envelopes. Any reference in the text or claims herein to a scaffold or envelope is limited to a device which has each and all of the following characteristics: (i) the device must be designed for arthroscopic insertion and implantation into a mammalian joint, such as a knee, hip, shoulder, etc; (ii) it must be flexible, in a way that renders it suitable for surgical implantation through a minimally-

invasive incision through a patient's skin; (iii) after the device has been inserted into a joint via a minimally-invasive incision, the device must be capable of being restored to a desired size and shape that is useful for replacing a segment of damaged or diseased cartilage in the joint; (iv) the device must have an envelope-type structure that allows it to be anchored to a bone surface in a relatively flat "unfilled" configuration, and subsequently filled with a hard-setting compound that will cause the resulting implanted device to provide a medically effective replacement for a damaged or diseased segment of cartilage; and, (v) it must be manufactured, packaged, and handled in a medically acceptable and sterile manner, to render it suitable for surgical implantation inside a mammalian joint.

As used herein, "arthroscopic" and "surgical" are used interchangeably. These are surgical implants, since they are implanted inside a joint by means that include cutting and physical manipulation of skin, tissue, and bone. These devices are also "arthroscopic" devices, which are intended to be implanted in a joint by means of minimally-invasive techniques, assisted by the use of arthroscopes to allow the surgeon to see what is being done inside a joint, beneath the skin. If desired, these devices disclosed can also be implanted into a joint by means of "open knee" surgical techniques, without using arthroscopic methods or devices. For example, if a joint suffering from multiple or disseminated damage has been opened up using classical techniques, one or more damaged segments of cartilage can be replaced using the same types of scaffold envelopes disclosed herein.

Femoral scaffold envelope 20 has an *articulating membrane* 22 (also called *outer* membrane 22) and also a *anchoring membrane* 24 (also called *bone* membrane 2 4). These terms refer to the positioning of a membrane after the device has been anchored to the end of a bone. An anchoring (bone) membrane will be pressed against a bone surface, while articulating (outer) membrane will provide an exposed articulating surface.

As shown in Fig. 4, tibial scaffold envelope 40 also has an articulating (outer) membrane 42, and an anchoring (bone) membrane 44. A preferred method for preparing a tibial anchoring surface 46 comprises grinding a portion of the tibial plateau off in a relatively flat and planar shape while sparing the raised tibial spine 96, to create anchoring surface 46. To accommodate that approach, which slightly reduces the height of the tibia bone 95 in the prepared area, tibial scaffold 40 is generally thicker than a femoral scaffold, and includes a vertical wall or rim portion 48, between the exposed articulating membrane 42 and the anchoring membrane 44. Except for those differences, any comments concerning

the design and fabrication a femoral scaffold envelope also generally apply to a tibial scaffold envelope.

Femoral scaffolds can have either curved or faceted anchoring surfaces. If a femoral bone is prepared in a rounded manner, as described below, the scaffold envelope should have an accommodating curved anchoring surface, as shown in Fig. 2. Alternately, if a bone surface is prepared in a faceted manner, with a plurality of flat faces 99 at controlled angles, the scaffold envelope 20A should have an accommodating faceted anchoring surface, as indicated by Fig. 3.

In one preferred embodiment, a tibial scaffold can have a flat anchoring surface, designed to lie securely against a flat and horizontal tibial bone surface, as illustrated in Fig. 4. Alternately, tibial scaffolds with curved or faceted anchoring surfaces can be used if desired, especially if long-term use indicates that curved or faceted anchoring surfaces help reduce shear forces and increase the durability of tibial implants.

In femoral scaffold envelope 20, as shown in Fig. 2, exposed membrane 22 and anchoring membrane 24 are sealed together around their entire periphery by a watertight seam 26, except for an inlet orifice connected to inlet tube 30 and an optional outlet orifice connected to optional outlet tube 31. The watertight seam 26 that couples membranes 22 and 24 to each other can be created by any suitable means (such as molding or heat-sealing) during the envelope manufacturing process.

The combination of a watertight seam 26 and inlet tube 30 allows a fluidized chemical compound or mixture (such as an epoxy, resin, or other polymeric or pre-polymeric compound or mixture) to be injected into the scaffold envelope 20, in a way that causes the compound or mixture to remain inside the envelope 20 without escaping in a manner that would contaminate the joint with unwanted material or debris.

For convenience, terms such as "polymeric mixture" or "polymeric substance" are used to refer to a compound or mixture which is injectable in a fluidized form, and which, after being injected into a scaffold envelope, will set and solidify into a final polymer having a desired stiffness and preferably non-rigid resilience. A polymeric mixture having these traits typically will contain at least one type of monomeric or other relatively small molecular building block, at least one type of chemical crosslinking agent, and if desired, an additional reagent to help ensure that the resulting polymer has a desired average chain length and desired levels of crosslinking and side-chains, to help ensure that the final polymer has the desired physical and mechanical traits after it has solidified, resembling the

natural properties of cartilage.

If desired, an optional outlet tube 31 can also be provided, to ensure that little or no air, inert gas, or other liquid or fluid remains entrapped inside the envelope, after the polymer has been injected into it. If an outlet tube 31 is used, one or more internal runners (discussed below) can be positioned inside the envelope in a manner that cause the runner(s) to act as baffles, to direct the movement of the polymer through the envelope along a single flow channel that leads from the inlet tube 30 to the outlet tube 31. This use of a baffle to create a single flow channel for the polymeric mixture will minimize the creation of any unfilled pockets of inert gas, saline solution, etc. If an outlet tube is not provided, the entire scaffold envelope 20 and inlet tube 30 can be packaged in a sealed airtight plastic wrapper, under vacuum conditions, to ensure that only very tiny quantities of a physiologically acceptable gas or liquid remain inside the scaffold envelope when it is implanted in a joint.

To help ensure proper filling of a scaffold envelope, it can be divided into several compartments, each having its own inlet tube (and optional outlet tube, if desired). For example, a scaffold envelope can use a "keel" structure that will extend below or beyond the anchoring face of the envelope, as illustrated in Fig. 15 for a patello-femoral joint, discussed below. This keel structure will fit into a groove that has been machined in the bone, to provide added stability and strength to the implant. If this approach is used, the keel structure can be a separate sealed compartment within the scaffold envelope, which can be filled with a polymeric mixture before the main body of the envelope is filled. This will allow the surgeon to ensure that the anchoring membrane of the scaffold envelope is properly settled into (and cemented onto) the correct position on the prepared bone surface, before the main chamber of the envelope is filled. In a second filling step, a second chamber comprising a rim structure, which surrounds the periphery of the scaffold envelope, can be filled, and adjusted as necessary for proper placement. In a separate third filling step, the center (and primary load-bearing) portion of the scaffold envelope can be filled with the polymeric mixture.

After the polymeric mixture has been injected into envelope 20, it will set (harden) into its final shape, inside the scaffold envelope. The resulting combination of a flexible polymeric envelope, which contains and covers a hardened non-rigid polymer, will provide a smooth-surfaced, non-brittle, medically effective replacement for a segment of damaged or diseased cartilage.

In one preferred embodiment, femoral scaffold envelope 20 is also provided with a

plurality of anchoring tabs 32, at spaced locations around the periphery of envelope 20, as shown in Fig. 2. Each tab is designed to accommodate a single anchoring pin that will be driven into the bone. Various types of bone-anchoring pins have been developed for other purposes, and are commercially available from various companies such as Mitek and Suretac.

Alternately, anchoring holes can be provided inside the rim of a scaffold, by means such as molded holes and recessed surface rings to accommodate the heads of anchor pins or other anchoring devices. This is shown by the internal placement of anchors 21 and 41 in femoral and tibial scaffolds 20 and 40.

In addition to using pin-type anchors to secure a scaffold envelope to a bone, the anchoring membrane 24 can also be cemented directly to a bone surface that has been prepared as described below, using a suitable cement such as a polymethylmethacrylate.

As used herein, phrases such as "permanently anchored to a bone surface" do not require use of anchoring pins, staples, or similar devices that penetrate a bone surface. For example, in frail and elderly patients suffering from osteoporosis or certain types of arthritis, it may be preferable to eliminate any anchoring pins or other devices that would penetrate a weakened bone surface. This would avoid or minimize the creation of additional holes in or other damage to the underlying bones. In such cases, use of a strong and non-resorbing cement which is selected and intended to create a permanent bond between a scaffold envelope and a bone surface is regarded herein as an alternate method of anchoring a scaffold envelope to the bone.

In addition, indirect means of anchoring a scaffold to a bone can also be used to permanently anchor a scaffold envelope to a bone surface. Examples of this approach, in which scaffold envelopes are cemented to anchored "positioning rings", are discussed below and illustrated in Figures 14 and 15.

STABILIZING PLATFORM AND MACHINING TOOLS

After a patient's leg has been anesthetized (such operations usually will not require general anesthesia), a device to assist in proper alignment and in the grinding, polishing, and other arthroscopic and surgical work, is secured to the patient's femur and tibia bones. An assembly 100 for doing this type of work is shown in Fig. 5.

In one preferred method of attachment, stabilizing platform 102 has two tibial pins 104 and 106, which emerge from the proximal surface of platform 102 (i.e., the surface

that is closest to the knee, when the platform is in place). After the patient's leg has been anesthetized, these two tibial pins 104 and 106 are driven through the skin on the front of the knee, below the joint line, and into the proximal surface of tibia (shinbone) 95.

This type of tibial platform, by itself, was developed for "total knee replacement" (TKR) surgery, and is widely used by knee surgeons. However, the additional components disclosed below, including the cam-hinged femoral attachments, are believed to be new; accordingly, this type of hinged knee alignment platform, with a fixed tibial attachment and a cam-hinged femoral attachment, is believed to be a new and useful invention in its own right. Because the claims are patentably distinct, the scaffold envelopes disclosed herein are claimed in one patent application, while the aligning devices are claimed in a separate simultaneously-filed application.

Two extension prongs 108 and 110 emerge from the lateral ends of tibial platform 102. These two extension prongs 108 and 112 are coupled, via two tibial hinges 112, to extensions 114, which are also coupled at their other ends to two femoral hinges 116. The two femoral hinges 116 are coupled to the two ends 118 and 120 of a metallic pin that has been driven through the femur bone 98, via incisions on both sides of the femur. Because of the cammed hinges, discussed below, this metallic pin, when emplaced directly through the femur, can interact with the other components of the alignment device to provide precise and reliable mechanical and anatomic alignment of the femur and tibia, even as the knee is flexed and extended. Accordingly, these devices can help a surgeon correct various problems that may be related to the patient's condition, such as a form of bow-leggedness that often results from arthritic damage to the knees.

This platform-securing procedure can be done while the patient's leg is kept straight, such as while the patient is lying horizontally on an operating table. The patient's knee is then bent, usually by lowering a segment of the operating table, so that the patient's calf and tibia are lowered into a vertical position, pointing downward, while the thigh and the femur bone remain horizontal. This movement of the knee joint and tibia allows access to the femoral condyles and the tibial plateaus, in the manner shown in the drawings. As the calf and tibia are being moved downward to a vertical position, the tibial hinges 112 and femoral hinges 116 rotate. This hinged mechanism allows platform 102 to remain directly in front of tibia 95, firmly attached to it via the two frontal tibia pins 104 and 106.

Tibial platform 102 contains at least two coupling receptacles (or other coupling devices) 126 and 128, mounted or positioned on the upper surface of platform 102, as

shown. These coupling means 126 and 128 are provided with connecting mechanisms (such as slotted holes or "bayonet" fittings), which can be used to temporarily but securely mount various devices (such as a "slotted burr guide" 130, discussed below) on top of platform 102. This arrangement allows a variety of interchangeable slotted burr guides and other devices and tools to be used during the arthroscopic procedure, to assist the surgeon while he works on the knee.

PREPARING BONE SURFACES

Before a flexible scaffold envelope as disclosed herein can be placed and anchored on a femoral condyle or tibial plateau, the bone surface that will be covered by the implant needs to be properly prepared. Typically, this will require (i) removal of any native cartilage from the femoral condyle or tibial plateau surface, so the implant can be anchored securely and permanently, without interference by a damaged or diseased segment of cartilage, and (ii) grinding and levelling the exposed bone surface to a properly shaped, relatively smooth surface, so that the weight of the patient's body, when placed on the patient's leg, will be properly distributed across the implant surface as the patient stands, walks, or engages in other activities after the knee has healed.

If the bone surface and the exposed implant surface are not properly shaped and machined during the arthroscopic procedure, the patient is likely to suffer from chronic or acute discomfort during walking or other activities, if the patient's entire weight comes to rest on an undesired protrusion inside the knee; this would be similar to the discomfort someone feels when walking on a heel with a bone spur. In addition, improper loading can cause or accelerate loosening of or other damage to the implant. Accordingly, proper preparation of the exposed bone surface where the implant will be positioned is essential to proper use of this invention.

As noted above, platform 102 (which is securely affixed to the tibial bone) has coupling receptacles or devices 126 and 128, mounted or positioned on the top surface of platform 102. These coupling means 126 and 128 allow an interchangeable "slotted burr guide" 130 and various other devices to be used during an arthroscopic procedure, to assist the surgeon.

A high-speed rotating tool can be used to remove cartilage and prepare a bone surface for an implant. A simplified depiction of the operating end of a grinding or polishing tool 150 is shown in Fig. 6, with shaft sleeve 152, and burr 154 mounted at the

end of an internal rotating shaft inside shaft sleeve 154.

These grinding tools are somewhat similar to a dentist's drill having interchangeable heads. The burrs, which have a variety of sizes and shapes, are usually made of very hard metal, and have a grooved, abrasive, or other surface that is suited for grinding, polishing, or similar use. The shaft has both an outer sleeve, which does not rotate, and an inner shaft that can rotate at relatively high speeds. The sleeve provided by the outer shaft also provides a means for suction removal of debris generated by a grinding operation.

These devices are commercially available from companies such as Dyonics, Arthrotek, and Arthrex, and are widely used in conventional arthroscopic procedures. Typically, burr-and-shaft assemblies that are roughly 20 cm long (about 8 inches) are used with a driving machine that has a hinged and movable arm. A fitting at the end of the arm allows various burr and shaft assemblies to be quickly connected to or disconnected from the machine arm, as needed. Because of the risk of clogging by bone chips and other debris, most burr heads used in arthroscopic procedures are disposable, and are discarded after an operation is completed.

Grinding tools also can be provided with an angled component, as shown in Fig. 7, so that a rotating angled burr 156 is mounted at an angle (such as a right angle) respective to the main shaft sleeve 158. This type of device can be provided by using a shaft assembly that includes (i) non-rotating outer sleeves, in two segments, (ii) rotating internal shafts, also in two segments, coupled to each other via conical gears or other suitable means. Alternately, this type of angled shaft assembly can use a chain-type mechanism which travels through the main shaft sleeve 158; the chain can drive a sprocket, which in turn will drive angled burr 156. As another alternative, a tool having the same net effect and operability can be provided by other means such as, for example using a tool with a gradual curve rather than a sharp angle, with a series of gimbal-type "universal joint" rotating components inside the outer sleeve.

GUIDES AND TEMPLATES

In the embodiment shown in Fig. 6, the tool shaft sleeve 132 passes through slotted burr guide 130, which is temporarily mounted on top of the stabilizing platform 102. Slotted burr guide 130 has a slot 131 passing through it. This slot 131 holds and constrains the shaft sleeve 132.

In one type of slotted burr guide, which can be regarded as an alignment or template

guide, the slot 131 in slotted burr guide 130 is only slightly larger (in its narrow dimension) than the diameter of non-rotating shaft sleeve 132. This prevents wobbling or other loose motion of the shaft in any undesired direction. The grinding burr 134 therefore can be moved back and forth across the length of slot 131, but the burr 134 cannot go beyond the reach of slot 131.

Fig. 9 shows a slotted burr guide with an even tighter constraint, comprising a square sleeve 160 that is part of the slotted guide assembly. This type of square sleeve 160, which can slide left or right inside slot 162, prevents any angling of a burr head in any direction, while allowing the burr head to be extended or retracted and moved solely to the left or right. This type of alignment guide can be used in preparing, for example, a flat and horizontal tibial plateau, on either side (or both sides) of the tibial spine (i.e., the small promontory in the center of the tibial plateau), as shown in Fig. 4.

Fig. 10 shows a slotted burr guide that allows the burr head to be tilted upward, but only at two specific vertical slots 164, positioned along the travel path of the slotted burr guide 166. This type of slotted burr guide 166 can assist in preparation of a flat tibial plateau that is provided with a groove at a fixed location (by angling the grinding tool downward at a vertical slot 164), to accommodate a scaffold envelope that has a "keel" structure as illustrated by the groove-and-keel arrangement shown in Fig. 15.

If desired, a slotted burr guide can also be provided with mechanical means (such as a detente inside slot 142, which interacts with a raised ring on rotating shaft 152) to limit and control the extension of the grinding burr 154 into the knee joint.

The types of slotted burr guides discussed above can be used, in conjunction with a device called a "goniometer", to create both (i) flat (i.e., single-planar) bone surfaces, such as for a tibial scaffold, and (ii) "faceted" bone surfaces, such as faceted femoral surfaces 99 as shown in Fig. 3. Faceted femoral surfaces are widely used in conventional "total knee replacement" operations, using open-knee surgery. A goniometer is a device that can precisely measure the angle of a knee, at any given position of flexion or extension. A goniometer can be used, in conjunction with one or more slotted burr guides, to create a set of vertical, horizontal, and angled (also called "chamfered") surfaces on a femoral condyle, as shown in Fig. 3. These facets can provide a solid and secure attachment for a femoral scaffold envelope having a faceted anchoring membrane.

In an alternate type of machining guide, a completely stationary clamp 130A (as shown in Fig. 7) can be affixed to the tibial stabilizer platform 102, to securely hold a shaft

sleeve 132A in an absolutely fixed position while the patient's foot and calf are slowly lifted and lowered by the surgeon, to rotate the knee joint and tibia while the femur remains stationary and horizontal. This type of stationary clamp 130A can be used with a grinding burr 134A that rotates at a right angle with respect to the main shaft sleeve 132A, as shown in Fig. 7, to prepare a femoral condyle surface. During this procedure, the patient will be lying flat on his back or sitting in a chair, with his thigh and femur bone horizontal. The calf of the patient's leg is moved up and down slowly, through various stages of flexion (i.e., where the knee is bent and the calf and tibia point downward) and extension (i.e., where the knee is straight and the calf and tibia are horizontal). As the calf and the tibia bone are slowly moved up and down, the rotating burr (which is securely affixed to the platform that is affixed to the front of the tibia bone) will be slowly moved across the surface of the femoral condyle, to grind away any cartilage and prepare the condyle to receive a scaffold implant. This will generate a smoothly rounded femoral condyle bone surface, which can accommodate the type of femoral scaffold envelope shown in Fig. 2.

If this approach to preparing the bone surface is used, it must be recognized that the femoral condyles are "cam" structures, i.e., they have a somewhat elliptical or cycloid shape with a varying radius, rather than being truly circular with a single radius. When the knee is fully extended and the leg is straight, the smallest portion of the cam structure articulates with the tibial plateau. As the knee is bent through progressively higher degrees of flexion, the distance between the center point of the femoral condyle and the outermost rim of the condyle grows larger, and the tibial plateau is pushed farther away from the center point of the femoral condyle, by the gradually increasing radius between the center point and the rim of the condyle. The cam differential varies between different individuals; in most adults, the cam differential is usually somewhere between about 4 mm and about 12 mm.

A rounded bone surface with the natural cammed structure can be generated using any of several approaches in the design of the stabilizing and aligning tools and guides. As one example, as shown in shown Figures 5 and 6, platform 102 can be coupled directly to the tibia bone 95 by means of fixed pins 104 and 106, and can also be coupled to the femur bone 90 by means of cam structures incorporated into femoral hinges 116. These femoral hinges 116 are positioned at the two ends 118 and 120 of a steel pin that has been positioned in a hole that has been drilled sideways through femur bone 90. Any suitable type of bracing or clamping system can be used to prevent the pin from rotating; for

example, a strap-on brace can be fastened around the patient's thigh, and this brace can be used to clamp both ends of 118 and 120 of the femoral pin, which can be provided with a faceted or other non-round or non-smooth surface, to ensure that it cannot rotate once it has been clamped.

If cammed femoral hinges 116 are provided on both sides of the femur, the two struts 114 will be pushed downward (toward the patient's foot) a small distance as the calf and tibia are moved from an extended (horizontal) position into a flexed (downward) position. This cammed extension preferably should be the same distance as the femoral cam differential in the patient; that distance can be determined, before an operation begins, by measuring an X-ray or MRI image.

Cammed femoral hinges 116 can incorporate any of several suitable mechanisms that will provide the desired result. In one such mechanism, shown in greater detail in Fig. 8, the head 142 that is mounted at each end of a non-rotating femoral pin 140 (driven transversely through femur bone 90, and securely clamped to prevent subsequent rotation) can comprise an actual cam disk, mounted in a plane that is perpendicular to the shaft provided by the pins 140. A strut 150 on each side of the knee can be provided with an anvil-type upper end 152, which will press and ride against the cam disk 142 as the knee is flexed or extended. To eliminate any undesired motion, the anvil 152 at the end of strut 150 can be held tightly against the cam disk 142, during rotation, by means such as a spring 154 which is coupled to a constraining device 156 coupled to strut 150. The lower end of strut 150 is coupled to a pin 158 which passes laterally through tibia bone 95.

The drawing of this structure in Fig. 8 is a simplified depiction, intended solely to convey a visual impression that the femoral pin terminates in a cammed device; in actual practice, a different cammed structure would likely be used. Various such devices are known for generating a cammed path of motion, such as devices which include (i) protruding pins that travel within slotted structures having the desired shapes, and (ii) rotating disks that are mounted in an eccentric (off-center) manner on an axle.

It should be noted that struts 114, as shown in Fig. 6, are angled somewhat, since the hinges 112, which flank the tibial stabilizing platform 102, are not in a direct line with the center of the tibial bone, and are offset from it in the anterior direction. If desired, any of several approaches can be used to accommodate for that fact while still providing anatomically precise alignment of the femoral condyles and tibial plateaus during a grinding procedure or other alteration. In one method, the size and shape of the camming structure

in the femoral hinges 116 can be adjusted somewhat, to account and adjust for the offset distance (i.e., in Fig. 6, the horizontal distance between the actual tibial hinges 112, and an imaginary centerline drawn through the center of the tibial bone at that same height).

As a second option, tibial platform 102 can be fitted with lateral extensions on both sides. These extensions can curve or otherwise extend partway around the calf and tibia, to a point where they can position the tibial hinges 112 in exact desired locations, on both sides of the tibial bone and squarely flanking it with no offsetting factor. If this second option is chosen, the tibial platform can be reinforced, to prevent or minimize any bending or torsional forces, by means of a clamping device that can be strapped around the calf.

Routine tests on animals or human cadavers can determine whether a simple adjustment to the size or mechanism of the cammed femoral hinges 116 will allow that approach to be used, since it may provide the simplest and easiest solution to any problems that might be caused by the tibial offset factor. Similar tests can also evaluate any other candidate approach to providing the cammed action discussed herein.

Using the various components and methods discussed above, various types of alignment guides can be used to carefully constrain the path and reach of a grinding or polishing tool inside a knee joint, while keeping the tibia and femur bones properly and precisely aligned. By moving the tool back and forth inside slot 142, a high-speed rotating burr is carried through a grinding or polishing path that generates a desired shape (flat, faceted, or curved) on a femoral condyle or tibial plateau, to ensure a close fit between the prepared bone surface and the scaffold implant that will be anchored to that bone surface.

In other types of slotted burr guides, a slot can allow a wider degree of motion by the shaft and the burr. This type of slotted guide can be used by a surgeon as a stabilizer, rather than a template, to give the surgeon a steady base for better leverage and control over the shaft 152 of the grinding tool 150. In a manner comparable to a photographer resting one elbow on a solid surface while holding a camera, this can help the surgeon exert better control over the grinding or polishing actions of the tool.

Various other types of mechanical devices (including devices referred to herein as "travelling guides", which move in a fixed and constrained path while tightly holding a tool) can also be used to guide and properly constrain the motion of a grinding or polishing tool. As one example, assembly 200, shown in Fig. 11, comprises a travelling guide 202 mounted between two fixed vertical supports 204 and 206, both of which are permanently mounted on a working platform 208, which can be detachably mounted on the tibial

stabilizing platform 102 shown in Figures 5 through 7.

Travelling guide 202 is coupled to the fixed vertical supports 204 and 206 via a total of four rotating struts 210-216, with two struts coupled to each side of guide 202 via a lateral pin 218. Each strut 210-216 can rotate about a first fixed pin or hinge 220 which is mounted on a fixed vertical support 204 or 206. In addition, the movable end of each strut is coupled to a second rotatable pin or hinge 222. This arrangement, as shown, allows all four struts to move together in a linked manner, coupled to the centered guide 202 which can travel upwards or downwards in an arc.

Travelling guide 202 is shown in a simplified manner, with orifice 230 passing through it to hold a burr shaft or other tool. In actual use, orifice 230 should be provided with a clamp or other securing device so that a burr tool can be placed in the guide and locked in securely, to avoid unwanted wobble, extension, or other motion during use.

This type of travelling guide can be used to establish a reproducible arc which is aligned in a way that can be used to prepare a femoral condyle for implantation of a scaffold envelope. If the lengths of all four struts are identical, and if the vertical spacing between the travelling pins 222 is identical to the vertical spacing of the fixed pins 220, travelling guide 202 will pass through a simple circular arc, having a radius equal to the lengths of the struts. By contrast, if the top struts 210 and 214 have a different length from the bottom struts 212 and 216, or if the vertical spacing between the travelling pins 222 is different from the vertical spacing between the fixed pins 220, then travelling guide 202 (and any grinding burr or other tool that is secured in the guide 202) can be given any of a variety of curved or elliptiform, yet constant and reproducible, pathways. Accordingly, this type of travelling guide can be used, to enable a surgeon to quickly and reliably generate uniform and predictable curved surfaces for mounting scaffold envelopes on prepared bone surfaces.

If desired, a similar approach can be used to grind precise and consistent rounded or elliptiform shapes in tibial plateaus, by altering the size and shape of the vertical supports 204 and 206 (if necessary) and by altering the placement of the fixed pins 220 so that they have a more horizontal alignment.

Any number of other types of alignment guide and/or templates can be used, if desired. As one example, a penetration guide 240 shown in Fig. 12 has a fixed horizontal base 242 with a track structure 244 that holds a slidable base 246, which can be securely clamped at any fixed location along the lateral span of fixed base 242, to establish a

working position. Slidable base 246 supports two fixed vertical supports 250 and 252, which are parallel to each other, similar to the supports 204 and 206 in Fig. 11 but closer to each other. Vertical supports 250 and 252 have matching parallel curved slots 254 and 256, as shown in Fig. 12. These matching slots 254 and 256 can have any desired shape and size, include any desired type of curve. A tool shaft (not shown) with a grinding burr at its tip is provided with two fixed lateral pins extending outwardly from each side of the shaft sleeve. These lateral pins will engage slots 254 and 256 in the vertical supports 250 and 252. The lateral pins on the tool shaft will be constrained within the parallel slots 254 and 256, and will be able to move back and forth only within those slots. Accordingly, the shape and curvature of the two slots 254 and 256 will control the pathway of a grinding burr or similar tool mounted at the tip of the tool shaft.

This type of penetration guide allows a surgeon to carefully and reproducibly control the path and travel of a grinding burr or other tool as it extends and penetrates farther and deeper into a joint being repaired. By contrast, the slotted guides shown in Figs. 6 through 10 will mainly control lateral motion of a tool.

Various other types of fixed or travelling guides, templates, and other aids that are useful and helpful for rapidly and reliably machining and shaping a hard surface into an exact desired shape are well known to machinists and mechanical engineers, and are used in various types of machines, machine shops, carpentry and furniture shops, etc. Such devices include mechanisms that are linked, by gears or other devices, in a manner which provides three-dimensional control over the path of a rotating burr.

Alternately or additionally, computerized control systems can also be used, in which a computer is programmed to operate a device that moves a rotating burr, laser, or other tool through a complex two- or three-dimensional pathway. This can be done, using hardware and software interactions that are comparable to what happens when a graphic plotter moves a pen or inkjet through a highly complex pathway while printing a map, blueprint, or other complex drawing. The hardware and software used in such computerized control systems are well known to people skilled in the art of designing and manufacturing computer-controlled machining systems and other computer-controlled mechanical devices.

Accordingly, the suitability of any known mechanical, electrical, or computerized control system, to help facilitate surgical and/or arthroscopic preparation of a bone surface so it can receive a scaffold envelope as disclosed herein, can be evaluated for use as disclosed herein by those skilled in the art, using no more than routine experimentation.

It should also be noted that a variety of different tool guides can be interchangeably mounted on tibial platform 102 during various different stages of the arthroscopic procedure. For example, a "femoral prep" set of devices can be used to help prepare a femoral condyle, and a "tibial prep" set of device can be used to prepare a tibial plateau. Subsequently, after the scaffold envelopes have been inserted, anchored to the bones, filled to the proper level with a hard-setting compound, and allowed to set into hardened configurations, "femoral finish" guides and tools can help the surgeon finish and fine-tune the femoral implant, and "tibial finish" guides and tools can help the surgeon finish and fine-tune the tibial implant.

Various other types of devices also can be used, in conjunction with a fixed stabilizing platform and interchangeable guides or templates, to complement and support any desired step in the arthroscopic procedure. For example, depending on the type of polymer or other material used to create an implanted scaffold, a curved spatula with an electric heating element, which renders the surface of the spatula hot enough to melt a thin outer layer of the implant scaffold, may be used to momentarily liquify the polished surface of an implanted scaffold, so that the melted surface layer, upon cooling, will harden into a surface that is smoother than can be obtained by abrasive polishing. Alternately or additionally, laser devices, razor-sharp slowly rotating blades which can cut cleanly through the solidified polymer, and other such tools can be used, rather than abrasive grinding tools, during the final fine-tuning stages of an operation.

In addition to removing the entire layer of native cartilage in the region that is to replaced by a synthetic implant, a surgeon can also remove a significant amount of the outermost bone surface. For example, in preparing a femoral condyle or tibial plateau, a surgeon can sculpt a "bed" in the bone, ranging from about 1 to 3 mm deep (about 1/16 to 1/8 inch) around the periphery of the bed, increasing to a maximum of about 6 to 10 mm deep in the center of the bed. This approach can help accomplish several goals. First, it can help provide a relatively flat and gradually-curved surface for anchoring the scaffold, instead of forcing the scaffold to adapt itself to each and every small variation or curvature in a bone surface. Second, it can help ensure that the scaffold is anchored solidly and securely to fully-hardened bone, rather than to an interface region where the bone tissue makes a transition to cartilage tissue. Third, it can allow the scaffold to be made thicker, which means it can be stronger and more durable than a thin layer, and it can provide better cushioning and shock absorption than a thin layer coated on top of a hard surface.

Fourth, it allows blunt edges to be provided around the periphery of the scaffold envelope, to avoid the need for fully angular tapers with paper-thin peripheral edges, which might become detached, frayed, or otherwise damaged. And fifth, it makes the anchoring process easier and more reliable, and avoids or minimizes any protrusions or surface irregularities that might jeopardize the success and durability of the cartilage replacement.

IMPLANTING, CEMENTING, ANCHORING, AND FILLING A SCAFFOLD

As noted above, two of the characteristics of a scaffold envelope suitable for use as described herein include: (i) it must be suited for insertion into a joint through a minimally-invasive incision, as commonly used in arthroscopic surgery, while the envelope is empty; and, (ii) after it has been inserted and properly anchored to a bone surface, it must be filled with a fluidized compound that will set and harden into a desired final shape, so that the resulting hardened structure can effectively replace a segment of diseased or damaged cartilage that has been removed by the surgeon.

In order to promote these goals, a scaffold intended for use as disclosed herein preferably should be manufactured in a way that causes it to seek and settle into a certain desirable shape. For example, an implant for a femoral condyle will have a certain shape and size, with a relatively pronounced curvature; by contrast, an implant for a tibial plateau will have a significantly lesser degree of curvature, and in one preferred embodiment will have an essentially flat anchoring surface.

Such scaffolds can be created by fabricating the scaffold envelope from a flexible material that has a "three-dimensional memory". This means that after it has been molded and set in a certain desired shape, it can be twisted, squeezed, or otherwise manipulated to allow insertion of the empty scaffold into a joint through a relatively small skin incision, with the aid of an insertion tube if desired. Subsequently, after the pressure, tension, or other force has been released from the scaffold, the rubbery elastic material will seek to return to its original molded shape.

Additionally, if desired, a scaffold envelope can contain one or more internal reinforcing structures. These can be similar to the internal straps and other devices used in inflatable air mattresses, to cause such air mattresses to inflate into relatively flat (rather than spherical) shapes. For example, if a femoral condyle scaffold is provided with several internal reinforcing straps, evenly distributed across the area of the envelope, those straps would provide substantial assistance in helping the envelope generate a desired, relatively

uniform thickness as it is inflated with a fluidized compound.

Alternately or additionally, a scaffold envelope can be provided with one or more internal reinforcing "runners" or "vanes" that extend parallel to the longest dimension of the envelope. As noted above, if this type of internal runner is used, it can also serve as a baffle, to provide a single flow path from the inlet orifice to the outlet orifice. In this design, polymeric fluid which is being injected into the scaffold will progressively force any gas or liquid in the collapsed matrix toward the outlet tube, as the envelope fills up with the injected polymer.

As yet another approach, a multi-chambered device can be provided, wherein each chamber tries to seek a certain size and shape as it is filled with the fluidized polymer.

Once a scaffold has been inserted into a joint, it is released from any squeezing or other constraint or force that was used to insert it through the skin incision. In some cases (for example, if a flexible scaffold was packaged and sealed under vacuum conditions), it may be easier to work with and manipulate the scaffold inside the joint if it is partially filled with the liquid polymeric compound, so it can assume a near-normal size and posture with no internal vacuum or other distorting forces on it, but without expanding to its completely-filled size.

Once the scaffold has been properly positioned over the prepared bone surface, to make sure they align properly and that both contacting surfaces are ready to be cemented together, a layer of a suitable cement that adheres tightly and permanently to both surfaces (such as a polymethylmethacrylate) is applied to either or both surfaces. The surfaces are then pressed together firmly, the scaffold is gently but firmly pressed and tamped down by the surgeon using an appropriate tool, and any anchor pins, staples, or other such devices are driven through any anchoring flaps or other accommodating components. The cement and anchors, working together, will permanently affix the anchoring membrane of the scaffold to the prepared bone surface.

After the cementing and anchoring steps have been completed, and after the cement has been given some time to at least partially set, the scaffold is then filled with the remaining desired quantity of polymeric liquid, to expand and enlarge the scaffold to its final desired thickness. While the injected polymer is setting and gradually hardening, the outer articulating surface of the scaffold can be manipulated and shaped in various ways, so it will have the desired final shape and contours after the polymer inside the scaffold fully sets and hardens.

To minimize the need for final polishing of a fully set and hardened implant, a surgeon can use various shaping and manipulating devices (both active and passive, such as spatulas, depressors, templates, shaping guides, etc.) to help ensure that an implanted scaffold is molded, pressed, or otherwise shaped or sculpted into a desired shape after the setting compound has been injected into the scaffold, but before it fully sets and hardens. For example, Fig. 13 illustrates placement of a passive surface guide 260, which can be inserted arthroscopically into a knee joint. During the polymeric filling operation, guide 260 is held in position by a mounting attachment 262, which is affixed to the tibial platform 102, and a positioning arm 264. This type of passive guide does not need to be large and wide; instead, its main purpose is to ensure that the center of the tibial scaffold 40 rises to the desired height, and no further, as it is being filled.

After the injectable compound has set into a final shape, the surgeon can use the various sculpting and cutting tools to finish and "fine-tune" the surface of the hardened scaffold into the desired final shape, as discussed above. The inlet tube (and outlet tube, if present) can be cut off from the scaffold envelope, using an arthroscopic scalpel or scissors inside the knee joint. This cut preferably should be flush with the surface of the envelope, so that a remnant of the tube does not protrude outwardly; however, so long as the tube inlet has been positioned properly, away from any articulating or load-bearing surface, a small blunt stump should not cause substantial problems. The remainder of the tube is pulled out of the knee joint, any additional work that may be necessary is completed by the surgeon. The skin incisions are closed and sutured, stapled, or otherwise secured, to complete the surgery.

POLYMERIC MATERIALS

Scaffold envelopes as disclosed herein can be made from any selected polymeric or other suitable material that has a suitable combination of flexibility, biocompatability (which includes traits such as low levels of thrombogenicity), strength, and resistance to wear and abrasion. A great deal of work has been done on biocompatible polymers, as reviewed in various publications such as Peppas et al 1994, Silver 1994, Hubbell 1995, Stokes 1995, Burg et al 1997, Lewis 1997, Kim and Mooney 1998, and Ambrosio et al 1998. Accordingly, various types of polymers having the desired combination of traits are known to those skilled in the art.

It also should be recognized that the final "stiffness" of most non-rigid polymers can

be controlled, to achieve nearly any desired level of non-rigid stiffness, by controlling various factors such as (i) crosslinking conditions, (ii) the type and concentration of any crosslinking agents that are mixed with a monomeric or pre-polymeric building block, and (iii) the type and quantity of other chemical agents that will truncate, quench, or otherwise modify a crosslinking reaction.

In general, the net result of controlling these factors (and other factors that are known to chemists and others who develop and design biocompatible polymers) is to control any or all of the following: (i) the average molecular weight of a resulting polymer; (ii) the density and chemical structure of the crosslinking bonds which couple long polymeric backbones to each other; and (iii) the length, density, and other traits of side chains that become wrapped around and entangled with each other, in the complicated molecular meshworks that generate most types of strong and resilient but non-rigid polymers.

Since scaffolding envelopes can be manufactured under completely non-physiological conditions, in a "clean room" type of factory or laboratory, a fairly wide variety of elastomeric polymer classes offer good candidates for evaluation for such use. Two particular types of elastomeric polymers that are likely to be well-suited for such use include polycarbonate polyurethanes, described in articles such as Stokes et al 1995, and perfluorinated elastomers, described in items such as US patents 4,621,107 and 4,900,793 (Lagow et al, 1986 and 1990).

A polymeric or pre-polymeric compound or mixture that is to be injected into a scaffold envelope preferably should set and harden at body temperatures, without requiring ultraviolet radiation, high temperatures, or other non-physiologic conditions. Such polymers are sometimes referred to as "cold-setting" polymers, since they do not require high temperatures. Since most crosslinking reactions are exothermic (i.e., they release energy), a cold-setting polymer may reach a somewhat elevated temperature, comparable to hot bathwater; however, such reactions generally should not create temperatures that reach or approach the melting temperature of a polymer.

In general, most types of "cold-setting" polymers that do not require prolonged curing times contain at least three chemical components: (i) at least one type of monomeric or other relatively small building block; (ii) at least one type of chemical crosslinking agent, which normally must be kept separate from the monomer until they are ready to be mixed together and injected as a mixture; (iii) optionally, an additional reagent to help

ensure that the resulting polymer has a desired average chain length and desired levels of crosslinking and side-chains, to help ensure that the final polymer has the desired characteristics after it sets and hardens.

Various polymeric mixtures that are mixed immediately before use (in a manner comparable to epoxy) can set and harden within less than an hour. By contrast, pre-mixed compounds (such as the silicon rubber compounds typically sold in tubes that fit into caulking guns) usually require substantially longer to set and harden, so that a solvent which keeps the compound in liquified form inside the tube can permeate out of the compound as it sets, once it is exposed to air. Since rapid setting times are very important whenever a patient is being kept anesthetized, polymeric compounds that require only about 5 to 15 minutes to set and harden are preferred over compounds that require more than an hour.

The filling polymer does not need to have very high levels of biocompatability, since it normally will remain completely sealed inside a scaffold envelope, and will not come into direct contact with tissues or body fluids. However, since there will always be some risk of damage to the knee (such as in an accident) that might somehow rupture the scaffold envelope, any polymer that is used in a surgical implant preferably should be biocompatible, in case any unplanned contact occurs between the polymer and any body fluids or tissues.

The filling polymer does not need to be made of the same material as the scaffold, so long as the filling polymer can form a strong and durable bond with a pre-formed surface inside the scaffold. If desired, the envelope and the filler polymer can be different types of polymers or other materials which have substantially different physical characteristics. For example, if desired, the scaffold envelope can be made out of a relatively soft and rubbery material, while the filler polymer is harder and closer to rigid; this would allow maximum flexibility and manipulation of a highly flexible unfilled scaffold envelope, during arthroscopic insertion and implantation. Alternately, a scaffold can be made of a relatively stiff material, for greater durability and resistance to wear and abrasion, while the filler material can be a softer and more elastic material, or a semi-liquid gel or polymer-gel mixture.

As another alternative, the articulating surface of a scaffold envelope can have a metallic external layer, which can function as both (i) a mechanical spring device, to help ensure that the envelope seeks and obtains its desired final shape after it has been inserted

into the knee; and (ii) a smooth and durable surface that is highly resistant to abrasion and wear. Such metal-coated scaffold envelopes can be modelled after the metal-on-plastic "total knee replacement" implants that are used under the prior art, using open-knee surgery.

PATELLAR IMPLANTS; PREPARATION AND SCAFFOLDING OPTIONS

As noted above, scaffold envelopes as disclosed herein also can be used to replace damaged cartilage segments on either or both of the articulating surfaces between the patella (the kneecap) and the femur. Because it is easier to illustrate the relatively simple patello-femoral compartment than the more complex femoral-tibial compartments, the discussion in this section is also used to describe and illustrate various options and enhancements that can be used with implants for femoral condyles or tibial plateaus, if desired.

Fig. 14 illustrates the use of two distinct implants on the patellar bone 298, as well as two distinct implants on anterior femoral surface 299. Patellar implant 300 comprises a positioning ring 302 (shown in cross-section as angled rim cross-sections 304 and 306), and a patellar scaffold envelope 310. Similarly, femoral implant 320 comprises a positioning ring 322 and a femoral envelope 324.

Positioning rings 302 and 322 are each made of a single rim-shaped piece of material, with tabs, lugs, or other extensions or components that can be secured to the bone by anchor devices 330, spaced at suitable locations around the rim (either inside the ring, outside the ring, or both).

A positioning ring 302 or 322 does not have an envelope structure, and is not inflatable. In a preferred embodiment, it has an open center with no membrane covering the middle, so that it can be easily manipulated and positioned by a surgeon during a positioning and anchoring procedure.

For each implant 300 or 320, after the bone surface has been prepared and the damaged segment of cartilage has been fully removed by a grinding operation as described above, the positioning ring 302 (or 322) is inserted into the joint, and carefully placed and positioned on the prepared bone surface. After the anchors 330 have been set into the bone, with the assistance of cement if desired, the ring is complete and ready to receive a scaffold envelope.

A scaffold envelope 310 (or 324) is then inserted through a skin incision into the knee joint in folded or rolled form. After insertion, it is unfolded or unrolled into a relatively flat unfilled shape. A suitable quantity of cement 340 is injected between it and

the prepared bone surface, and the cement is spread evenly across the contact surface, using a device such as a spatula tip. To help stabilize and strengthen the cemented attachment, one or more grooves or holes 342 can be drilled, grinded, or otherwise created in the bone surface, as shown by cement holes 342; if such indentations were created, they are carefully filled with cement. The anchoring membrane 310A (or 324A) of the scaffold envelope 310 (or 324) is then pressed against the wet cement that covers the bone surface, inside the positioning ring 302 (or 322).

After the cementing operation, envelope 310 (or 324) is filled with polymeric compound 350, causing the envelope to expand to a desired final shape. If desired, the scaffold envelope 310 or 324 can also be provided with anchoring tabs; alternately, if animal and clinical tests indicate that pin-type anchoring of the envelope is not necessary, and gluing is sufficient in combination with a positioning ring (this may be valid either for certain types of patients, such as elderly patients who will not subject the joint to severe stresses, or possibly for all patients), it may be possible to eliminate anchoring of an envelope 310 or 324. In such cases, permanent securing of the envelope would rely on cementing in conjunction with the positioning ring.

Fig. 15 shows a similar set of patello-femoral implants, illustrating two significant differences. Patellar scaffold envelope 370 is coated with a metallic layer 372. This dome-shaped layer is thin enough to allow it to be flexed and bent into a somewhat flattened semi-circle configuration, to allow it to be inserted into a knee joint through a minimally invasive incision.

In addition, femoral implant 380 is provided with a "keel" 382 on its anchoring surface. Keel 382 extends into a groove or hole 384, which has been grinded or drilled into the anterior surface of femoral bone 299. This arrangement increases the stability and strength of the anchoring for the implant. As mentioned above, this type of approach can also be used to increase the stability and strength of other types of implants as well, including implants on femoral condyles or tibial plateaus.

It should also be noted that the positioning rings discussed above may also be useful in at least two other ways; accordingly, they are claimed herein in their own right.

First, a positioning ring can be marked, with a plurality of visible markings, to help them serve as location guides during an arthroscopic procedure. The difficulties and complexities of working arthroscopically inside a knee are considerable, in view of the complex obstacles posed by the numerous tendons, ligaments, and other forms of soft tissue

in and around the knee joint. Accordingly, a convenient positioning guide in the shape of a ring with calibrated marks on it, if properly positioned in the area that is being worked on, would in quite a few cases be a very useful aid to the surgeon.

Second, positioning rings can also enable another type of surgical correction, involving so-called "salvage operations", most commonly used in frail and elderly patients whose ligaments and connective tissues around the knee joint are fragile and tenuous. In patients who have already suffered severe deterioration around the knee, any surgical intrusions that disrupt any of the remaining tissues in or around the knee, more extensively than is absolutely necessary, can seriously decrease the likelihood of a satisfactory recovery. Accordingly, in some patients that fall into this category, it may be preferable to simply inject a cold-setting polymer into a horizontal basin, formed by an anchored positioning ring as disclosed above. This approach would dispense with the sealed scaffold envelope, and instead would use the positioning ring to establish an open scaffold, comparable to the wooden or steel forms (also called scaffolds) that are used to shape concrete when it is poured.

CARTILAGE REPLACEMENT IN HIP JOINTS

The invention disclosed herein can also be used to replace damaged cartilage in hip joints, and in shoulder joints, both of which involve "ball-and-socket" structures.

As illustrated in nearly any book on anatomy, in the hip, the uppermost end of a femur bone has a generally spherical convex surface (often called the "head" or the "ball"), at the end of an extended "neck" portion that has a smaller diameter than the head. The femoral head presses against a rounded concave surface (socket) called the "acetabulum", in the pelvis. Both the femoral head and the acetabular socket are covered by cartilage.

Arthroscopic methods for replacing the entire convex cartilage surface on the femoral head (in a hip joint) are illustrated in Fig. 15. The relevant portions of femur 480 include neck region 482, head (or ball) 484, and a damaged femoral cartilage surface 486. The relevant portions of a pelvis 490 include acetabular socket 492, and its cartilage surface 494. When an arthroscopic procedure of this nature is carried out, in most cases, it is likely to be necessary to replace both of the cartilage surfaces 486 and 492, even if only one of the two surfaces is actually damaged or diseased, since the steps involved in removing and replacing the cartilage on either surface is likely to damage or abrade the other cartilage surface as well. This is a common situation in any type of hip repair, since any damage or

irregularity on one cartilage surface is very likely to generate abrasion and damage on the other cartilage surface as well.

At the beginning of surgery, after the patient has been anesthetized, a strong tensile force (longitudinal traction) is placed on the leg, to open up a gap (usually about 2 to 4 mm) between the femoral cartilage surface 486 and the pelvic cartilage surface 492. A center portal 500 (also called a "trans-osseous" portal, since it passes directly through a hard bone structure on femoral ball 484) is then drilled through the main axle of the neck 482 and ball 484 of femur 480. This can be done by first inserting a guide wire 502 (which is actually a stiff steel pin, rather than a flexible wire) through the neck of the femur. This is done with the aid of a fluoroscope, which can be regarded as a video camera (i.e., it takes moving pictures, which are seen on a monitor screen) that takes "real-time" or "live" X-ray pictures, to indicate where the bones and soft tissue are as the guide wire passes through them.

After the guide wire 502 passes through a small incision in the skin, it is inserted through a hole which has been drilled through the hard outer layer of femur 480. After the guide wire 502 passes through that layer, it enters the "cancellous" bone, which is softer and largely made up of bone marrow, inside the femur bone. It can be drilled up through the neck of the femur, into optimal position.

After the guide wire 502 has been placed correctly through the bone, a moderately long, hollow cylindrical drill bit 504 can be used to remove a "bone core" (also referred to sometimes as a dowel), which is a tubular segment of bone and marrow that remains cohesive and intact. After the surgery has been completed, this bone core can be replaced back in the portal or tunnel from which it was removed. If properly replaced in position, it will heal again, usually within 6 to 12 weeks, to restore the femoral bone structure. The drill bits used in this procedure usually have diameters ranging from about 8 mm (for small adults) to about 14 mm (for large adults), and are usually about 30 cm long. Thes etypes of guide wires and hollow drill bits are known in the art, and are used during the conventional repair of various types of hip fractures.

After these steps have be used to create a tunnel or "portal" through the neck and head of the femur, a center portal tube 530 (shown in Fig. 18; also see center portal tube 602, shown in a slightly different structure illustrated in Fig. 19) can be emplaced through the tunnel that has been drilled through the femoral neck. This tube will have a hollow cylindrical wall, made of surgical steel or other suitable alloy, graphite, or plastic. Center

portal tube 530 (or 602) will be used for several purposes, including inflow and outflow of fluids, visualization using a fiber optic lights and arthroscopic camera, and machining. Since the flanking portals (discussed below) will not pass through hard bone, this center portal is also referred to as a "trans-osseous" portal.

One or more grinding and finishing tools, such as tool 510 as shown in Fig. 17A through 17C, can be introduced into the joint through the center portal. Tool 510 has a rotating inner shaft 512, a non-rotating sleeve 514 which is firmly attached to an external gripping component 516 which remains outside the patient's leg, and an operating tip 518 which is retractable (so that it can pass through a moderately thin access tube) and extendable (to allow it to be enlarged, radially, to carry out its work when it reaches the proper location inside the joint).

Reversible retraction or extension (expansion) of the operating tip 518, as shown in parts A-C of Fig. 17, can be provided by any suitable means, such as: (i) using an umbrella-type sliding device mounted in the shaft; (ii) causing the operating tip to extend outwardly when a control mechanism mounted in the handle is rotated in one direction (such as clockwise), and retract when rotated in the opposite direction; or (iii) causing the operating tip to extend outwardly when the tip itself is rotated in one direction (such as clockwise), and retract when rotated in the opposite direction. Such mechanical devices can be designed and manufactured by those skilled in the arts of mechanical engineering and arthroscopic tool design and manufacture. If desired, a release can also be provided, in case the mechanism becomes jammed by debris; for example, the operating tip 518 can be provided with a device that allows it to collapse in a manner comparable to a blown-out umbrella. After extraction of the reamer, the debris can be removed and the procedure can be continued.

As depicted in Fig. 18, the abrasive surface of the operating tip 518 of the grinding tool 510 will be rotated as the controlled extension of the grinding surface is carried out, to finish the grinding operation.

Fig. 18 depicts a lateral view of a three-portal device used in this invention. The center portal tube 530 passes through femoral neck 482, and will hold the shaft of cartilage removal tool 510. Collar device 532 is coupled to the exposed end of the center portal tube 530. Collar device 532, in conjunction with flanking struts 534 and 536, establishes the positions of two flanking portals 540 (comprising collar 542 and hollow tube 544) and 550 (comprising collar 552 and hollow tube 554). The two flanking portals 540 and 550 are

positioned to provide access to the anterior and posterior sides of femoral ball 484.

Fig. 19 illustrates a slightly more complex external guide 600, having a center tube 602, an inner (proximal) crossbar 610, and an outer (distal) crossbar 620. Crossbars 610 and 620 are firmly attached to the center tube 602. Inner crossbar 610 has pivot rings 612 and 614 at its opposed ends. These pivot rings 612 and 614 fit in a snug manner around the outer shafts 630 and 640 of movable grinding tools which can be inserted through the pivot rings 612 and 614, thereby allowing the pivot rings 612 and 614 to serve as fulcrum points which cause tool shafts 630 and 640 to function as levers.

Outer crossbar 620 also has curved travel guides 622 and 624 at its opposed ends. Since the pivot rings 612 and 614 (positioned near the middles of tool shafts 630 and 640) fit snugly around the outer shafts of tools 630 and 640, any motion of the outer (distal) end 632 of tool shaft 630 will generate a levered "mirror-image" motion of the operating tip 634, at the anterior or posterior side of femoral head 484. In this manner, a properly-shaped travel guide 622 helps a surgeon guide and control the motion of operating tip 634 of tool shaft 630. Accordingly, the outward-directed curvature of travel guide 622, illustrated in Fig. 19, helps ensure that the motion of the grinding tip 634 of tool shaft 630 conforms to a curved travel path that follows the curved outer surface of femoral head 484.

Similarly, curved travel guide 624 will interact with the distal end 642 of tool 640 to help ensure that the grinding tip 644 of tool 640 conforms to a desired travel path that follows the opposed surface of femoral ball 484.

Alternately or additionally, slotted guides or any other type of template or guide can be used, instead of open guides 622 and 624, to further constrain and control the pathway of a grinding or other tool inside the hip joint.

The flanking ports, which will not pass through any hard bone structure, can be used to allow access into the hip joint for a variety of cutting or grinding tools (such as grinding tool 680, which has a rotatable inner shaft 682 coupled to a grinding tip 684, a non-rotating outer sleeve 686, and a non-rotating external collar 688), or for any other desired arthroscopic instrument, such as lavage or suction devices, a fiber-optic light source or miniature lens, etc.

Rotatable inner shaft 682 in this device is provided with an angling mechanism 690, to allow the rotating grinding tip 684 to be angled in a controlled manner with respect to the main axis of sleeve 686, as indicated in Fig. 20B. This can be done in various ways that are known to the makers of arthroscopic tools. For example, angling mechanism 690

can comprise a sleeve which is pre-disposed to bend at a fixed angle. It can be straightened by exerting force on it, allowing it to be passed through a portal tube, and when it emerges from the end of the tube, it will seek to bend and reach its pre-disposed fixed angle.

In an alternative design, a flexible, non-rotating, thin "angle control strap" of bendable but non-stretchable steel or other alloy or graphite can be passed through a thin, flat sleeve on the inner side of the main shaft of tube 686. When the angle control strap is relaxed and released, the angling mechanism 690 will remain straight and aligned with the main shaft of tube 686. The distal end of the strap can be affixed to a non-rotating "chin" location near the end of the mechanism 690. When the strap is pulled out taut by the surgeon, it will pull at the fixation location at the "chin" location of mechanism 690, and will pull force the angling mechanism into an angle which can be varied and controlled throughout the operation, by controlling how far the angle control strap is pulled out during that stage of the operation. The rotatable grinding bit 684 can be mounted at the end of a rotating inner shaft which is made up of links coupled together by means of "universal" (gimbal-type) joints or any other suitable mechanism.

Another type of tool 700, which can be used in for cartilage removal in a hip or shoulder joint, is depicted in Fig. 21. This tool 700 comprises a rotatable inner shaft 702 which passes through a non-rotating sleeve 704 and collar 706. A brush-type bristles or brush assembly 708 is mounted at the tip of shaft 702, in a manner which allows the brush or bristles to be retracted (as shown in Fig. 21A) or extended (as shown in Fig. 21B) into and out of the non-rotating sleeve 704.

If desired, additional flanking portals can be provided. For example, 3 flanking portals can be provided, spaced apart from each other at any desired locations around the center portal, to provide access to the anterior, posterior, and superior (also called "cephalad") positions.

Accordingly, a center access port 500 is supplemented by at least two flanking ports, positioned at the anterior and posterior sides of the femoral head. These three (or more) access ports, working together, will allow a surgeon to completely remove both the femoral and acetabular cartilage surfaces in a hip joint, using various types of cutting and grinding tools (such as grinding tool 510 and brush tool 700), in conjunction with gripping, suction, and lavage devices for removal of debris, and with the support of other arthroscopic instruments for lighting, inspection, and other purposes.

In the acetabular socket, the cartilage removal procedure preferably should create a

generally spherical surface of hard bone, to which a synthetic envelope can be securely anchored. On the femoral head, cartilage removal can create any desired shape, ranging between a spherical shape which emulates the head of the femur, to a completely flat surface which replaces as much of the femoral head as the surgeon chooses. In a patient with healthy bone underlying the cartilage surface, removal of only a relatively small amount of bone is likely to be preferred, while in a patient suffering from osteoporosis, necrosis, or other damage in the underlying bone, arthroscopic replacement of essentially the entire femoral head and even a portion of the femoral neck may be preferred. In general, a faceted, conical, or rounded interface between a hard bone surface and a polymeric implant will provide better resistance to shear forces than a simple flat surface, partly due to the non-planar geometry of spherical, conical, or faceted interfaces, and partly because the contact area of a sculpted interface is larger than the contact area of a simple flat interface.

After the cartilage surfaces have been completely removed from both the head of the femur and from the acetabular socket, a first flexible empty envelope 802 (illustrated in Fig. 22) which is designed to replace the acetabular cartilage, is pushed into the cleared joint space, through any suitable access portal (normally this will be the center portal, since it will have the largest diameter). The flexible acetabular envelope 802 is made of a synthetic biocompatible polymer, so that it can be pushed into the joint space through an insertion tube, in a rolled-up and/or flattened configuration. After it enters the joint space, envelope 802 is unrolled and positioned over the prepared pelvic bone surface, with the help of gripping devices inserted through the flanking portals. It is then firmly and permanently anchored to the pelvic bone surface, preferably using a combination of cement and anchoring pins, to ensure strength and durability.

After envelope 802 has been positioned and anchored to the bone, a pre-polymeric slurry or paste 804 which will set and harden into a solid polymer at body temperature is then injected into envelope 802, in a manner similar to the means described above for the repair of knee joints. If desired, envelope 802 may also contain a series of discrete chambers, each of which is coupled to its own inlet tube. This would allow an envelope to be filled with a polymeric paste in various stages (such as in concentric rings, beginning with the outer periphery and working toward the middle), to help ensure that the filled implant, when completed, has exactly the desired final shape and fullness.

After the acetabular envelope 802 has been anchored and filled, a flexible femoral

envelope 810 is then inserted into the joint space, in an empty, rolled-up configuration, through an insertion tube. It is then anchored to the prepared bone surface of the femoral ball, and filled with a pre-polymeric slurry or paste 812 which will set and harden into a solid polymer at body temperature.

To close up the joint and complete the operation after the two cartilage replacement implants have been created, the center access port 500 that was drilled through the femoral neck must be closed up in a proper manner. In most operations, this can be done by replacing the core (dowel) of bone and bone marrow that was removed from the femoral bone at the start of the operation, when a hollow cylindrical drill bit 504 was used to drill the center access port 500, as described above. If that closure method is not available, the center access port 500 can be filled with a synthetic material, or with a biodegradable matrix made of bone fragments, collagen, and other suitable biological materials that will be resorbed and converted back into regenerated bone by the patient's cellular processes. If a synthetic replacement is left in the tunnel, a "cap"-type securing and protective device 820 can be attached to it, on the outer surface of the femur bone, as shown in Fig. 22. If desired, this protective "cap" 820 can be affixed to a reinforcing metallic component, inserted into the bone dowel or synthetic implant, by any suitable means. This would allow tension to be exerted on the implant envelope, to ensure that it remains pressed hard against the femoral bone surface.

Any of numerous types of devices in use today for repairing hip fractures (such as Gamma or Alpha nail intramedullary rods, as sold by companies such as Howmedica) can be used to provide additional intramedullary or other support for such procedures. These rods and similar devices can also be used at a later date, if a hip which has been repaired as disclosed herein suffers an inter-trochanteric or femoral neck fracture.

If desired, an acetabular cartilage surface can be replaced by an essentially round and symmetrical implant. Alternately, in another preferred embodiment, Fig. 23 depicts an acetabular socket 830 with an implant 840 that has a raised and/or metallic "horseshoe" (or inverted U) facing surface 842 on its exposed articulating surface. This would mimic the shape of the natural cartilage surface in an acetabular socket. The natural shape of the cartilage surface in a healthy unmodified acetabular socket suggests that the horseshoe design may be able to reduce wear on the femoral head, and prolong the useful life of a synthetic implant. In addition, such results from open-surgery operations also suggest that slightly reducing the diameter of the femoral head implant 850, compared to the diameter of

a native unmodified cartilage-covered head, may also be able to reduce wear on the joint surfaces and prolong the life of an implant.

In addition, an acetabular implant 840 with an inverted-U facing surface 842 would also make it easier to insert a flexible unfilled implant envelope which has a metallic load-bearing surface bonded to the polymeric envelope. This would create a metal-on-plastic load-bearing joint. Metal-on-plastic devices are preferred in conventional "total hip replacements".

CARTILAGE REPLACEMENT IN SHOULDER JOINTS

Like a hip joint, a shoulder joint also contains a ball-and-socket structure. In the shoulder, the upper end of the humerus (i.e., the large bone between the elbow and shoulder) has a rounded head (ball) at its upper end. This humeral head presses and articulates against a concave "glenoid" disk, which is essentially a socket that is relatively shallow, to allow the arm to have a wide range of motion. The shallow glenoid socket is part of a scapula (shoulder blade). The humeral head and the glenoid socket are covered with cartilage surfaces, which articulate against each other.

Essentially all of the comments above, regarding cartilage repair in hip joints, also apply to repair of cartilage surfaces in gleno-humeral joints in shoulders. A center access port can be drilled through the short "neck" structure which supports the humeral head, and two (or more) flanking access ports can also be established, which do not pass through hard bone. The entire cartilage surfaces on the humeral head and in the glenoid socket can be removed, and replaced by synthetic polymeric envelopes. Both of the flexible polymeric envelopes can inserted into the joint through an insertion tube, while they are rolled-up and empty; the glenoid envelope normally would be inserted, anchored, and filled first, before the humeral envelope, if both surfaces are being replaced in a single operation. After an envelope is unrolled, properly positioned, and securely anchored to the prepared bone surface, it can be filled, using an inlet tube, with a pre-polymeric slurry. The slurry will set and harden into a solid polymer, to create a stiff but non-rigid filled implant that replaces the cartilage which was removed.

Figures 24 through 26 depict an alternate preferred method, in which a stabilizing platform 910 is firmly secured to a humeral bone 900 by means of two fixation pins 912 and 914. Two slotted templates 920 (with grinding tool 922 passing through slot 924) and 930 (with rotatable coupling 932) are coupled to stabilizing platform 910. In a manner

directly comparable to the tibial stabilizer platform 102 and tool guide 140, shown in Fig. 6, this humeral stabilizer platform 900 and slotted templates 920 and 930 can assist a surgeon while he (or she) is grinding or otherwise removing cartilage from inside a shoulder joint, or aligning, anchoring, or filling a polymeric implant that has been placed inside the joint after the cartilage has been removed.

In a humeral joint, this type of access, via one or more flanking access routes as indicated in Fig. 24, can be used without requiring the "crossbar" structure shown in Fig. 19. The crossbar device is designed for working deep inside a hip joint, in a location which is quite a bit farther from the skin. In a humeral-glenoid joint, the cartilage areas are much shallower and closer to the skin; accordingly, devices and methods developed for workin on a knee are more likely to be suitable.

The approach illustrated in Fig. 24 can be used to help a surgeon create a synthetic keel structure 940 beneath a humeral surface implant 942, as shown in Fig. 25, to provide greater stability for the surface implant 942. In some patients, this approach may be able to eliminate any need to drill through the humerus and remove a bone dowel; in other patients, it may be preferable for a surgeon to use both approaches, for maximal access.

SYNTHETIC ENVELOPES WITH SEMI-PERMEABLE OUTER MEMBRANES

In one preferred embodiment, a synthetic polymeric implant can be provided with a semi-permeable surface membrane (on its articulating surface) which interacts with certain molecular components of synovial fluid (i.e., the fluid which naturally fills and lubricates the contact surfaces between two cartilage segments in a joint). These membrane-fluid interactions in a joint with a synthetic implant are intended to mimic the natural membrane-fluid interactions in a healthy and unmodified mammalian joint.

This approach is intended to ensure that a synthetic implant will constantly remain wet on its articulating surface. If two totally impermeable polymeric surfaces are placed in compressed articulating opposition to each other, they may suffer from a periodic or occasional tendency to "catch" or "grab" each other (i.e., to resist a smooth and natural type of motion), if the person has been standing motionless for a substantial period of time, in a manner which causes the two slightly-yielding and deformable rubbery surfaces to press hard against each other, in a manner which squeezes out the synovial fluid that normally lubricates the cartilage surfaces in a knee.

When that happens, the area of non-lubricated contact between the synthetic

polymeric surfaces will be relatively small, due to the geometrical shapes of the two femoral runners against the corresponding gutters of the tibial plateau. Accordingly, any such "dry spot" can usually be eliminated fairly quickly and easily, if the person will simply lift that leg for a second or two, so that the weight of the calf and foot will impose tension rather than pressure on the knee joint. This tension will cause fluid to re-enter the articulating surface, and re-wet the dry spot.

Nevertheless, the constant goals of surgeons, surgery, and biotechnology are to improve upon prior technology and to eliminate any and all design limitations, to a point where a surgically-created artificial structure or repair can fully emulate and duplicate the optimal design and behavior of a completely healthy problem-free natural structure.

Accordingly, semi-permeable outer membranes as disclosed below can be used to create synthetic cartilage-replacement devices which have exposed articulating surfaces that will remain wet over their entire surfaces, regardless of how long a repaired joint has remained motionless under compression.

To fully understand this approach, one needs to have a working knowledge of certain physiological and fluid-flow aspects of healthy and unmodified cartilage surfaces in a joint such as a knee. The overview provided below (which is necessarily brief and highly simplified) is an analysis by the inventor/applicant herein, based upon numerous published articles. Those articles can be grouped into three major categories.

In the first category, articles which focus mainly upon non-fluid structural components of cartilage (either in naturally-occurring healthy form, or in diseased form) include Teshima et al, *J Bone Joint Surg Br 77*: 460 (1995), and Guilak et al, *J Orthoped Res 12*: 474 (1994).

In the second category, articles that focus mainly on the liquids which help lubricate a joint, or on the interactions between liquids and various fibers, membranes, etc., include Setton et al, *J Biomech 26*: 581 (1993), Oloyede et al, *Connect Tissue Res 29*: 251 (1993), Bernich et al, *Biochim Biophys Acta 448*: 551 (1976), Torzilla, *Med Biol Eng Comp 31 Suppl*: S93 (1993), Oloyede et al, *Connect Tissue Res 30*: 127 (1993), Murakami et al, *Proc Inst Mech Engr [H] 212*: 23 (1998), Hou et al, *J Biomech 25*: 247 (1992), Hlavacek, *J Biomech 28*: 1199 (1995), Higaki et al, *Proc Inst Mech Engr [H] 212*: 337 (1998), Williams et al, *Proc Inst Mech Engr [H] 207*: 59 (1993), Schwarz et al, *Br J Rheumatol 37*: 21 (1998).

In the third category, articles which focus on artificial devices that have been

developed in the past (including artificial joints, candidate materials for use in joint repair, and cellular transplants) include Fisher et al, *Proc Inst Mech Engr [H] 205*: 73 (1993), Unsworth, *Proc Inst Mech Engr [H] 205*: 73 (1991), Williams et al, *Biomaterials 16*: 1169 (1995), Auger et al, *Proc Inst Mech Engr [H] 207*: 25 (1993), McClure et al, *Proc Inst Mech Engr [H] 210*: 89 (1996), Stewart et al, *Proc Inst Mech Engr [H] 211*: 451 (1997), Williams et al, *Proc Inst Mech Engr [H] 211*: 359 (1997), Gu et al, *Biomed Mater Engr 8*: 75 (1998), Ambrosio et al, *Proc Inst Mech Engr [H] 212*: 93 (1998), Corkhill et al, *J Biomater Sci Polym Ed 4*: 615 (1993), Oxley et al, *Biomaterials 14*: 1064 (1993), Badiger et al, *Biomaterials 14*: 1059 (1993), Szleifer, *Biophys J 72*: 595 (1997), Baker et al, *Cell Transplant 6*: 585 (1997), and Dror et al, *Biomater Devices Artif Organs 7*: 31 (1979).

The abstracts of all of these articles (and, indeed the complete texts of many of the articles they are abstracted from) can be obtained for free through the Internet, using one of the National Library of Medicine's search engines, such as at http://www.ncbi.nih.gov or http://www.igm.nih.gov.

Several acronyms and abbreviations that are commonly used in these and similar articles are worth noting, as follows: SF, synovial fluid; HA, hyaluronic acid, and its ionized or salt form, hyaluronate; DPPC, dipalmitoyl phosphatidyl-choline; SAPL, surface-active phospholipid; IPN, inter-penetrating network.

Briefly, the major components of synovial fluid (SF) inside a joint (such as a knee joint, which is used for purposes of illustration) include the following:

(1) water, which should be regarded as both a lubricant and as a solvent fluid, and which contains and carries various "macromolecules" that make the lubricant more slippery and viscous than plain water.

(2) hyaluronate (HA) molecules. These are naturally occurring polymers, with molecular weights ranging from about 50,000 up to about 8 million daltons. A molecule of hyaluronate normally is formed by stringing together a large number of alternating rings of glucosamine and glucuronate.

(3) monomeric and short-chain forms of glucosamine, glucuronate, chondroitin, and other relatively small molecules that form the building blocks of cartilage, hyaluronate, and other naturally-occurring compounds; and,

(4) two compounds called "lubricin" and "surface-active phospholipid" (SAPL). These two types of molecules exist in both free form, and in a "complex" form that is held together by inter-molecular attraction rather than covalent bonding. In a lubricin/SAPL

complex, a single molecule of lubricin is assumed to bind to a single molecule of SAPL. A lubricin/SAPL complex can be sheared apart or otherwise pulled apart by fluid flow or mechanical stress, without damaging either type of molecule. After this type of separation, it is assumed that the free molecules of lubricin and SAPL can recombine again, in solution.

Those are the primary known lubricating components of synovial fluid which are essential to understanding the statements and proposals in this application. They're shown in simplified schematic form in Figures 26A through 26F.

Fig. 26A, labelled "Unloaded Joint Space", is a cross-sectional depiction of a small portion of a knee joint that is relaxed and not under pressure. The top and bottom "selectively permeable membranes" shown throughout Figs. 26A through 26E represent only the outermost membranes that cover the opposing ("articulating") surfaces of two different segments of cartilage, on two different bones. In each part of Fig. 26, the upper membrane covers the bottom surface of a femoral runner, while the lower membrane covers the upper surface of a tibial plateau.

As indicated in Fig. 26A-E, these two membranes (which cover two different opposing segments of cartilage) do not contact each other at all; instead, there is a gap between them. That gap is filled with synovial fluid, which contains water (the solvent) and the slippery components of a biological "soup", which includes hyaluronate molecules, lubricin/SAPL complexes, and various other molecules such as glucosamine, chondroitin, etc.

The outermost membranes which cover the femoral and tibial cartilage segments are "selectively permeable". In general, each cartilage membrane is composed of a thin layer, made up mainly of interconnected collagen fibers. Collagen is a fibrous protein, which forms the matrix that holds cells together in nearly all types of cohesive flexible tissue, including muscle tissue, skin, organs, etc. Each thin membrane made of interconnected collagen fibers allows water molecules to flow through it in a rate-controlled manner; as discussed below, this allows fluid loads and pressures to be redistributed across the membrane in a regulated manner as the joint is "loaded" with weight.

Each collagen membrane also allows some but not all of the "macromolecules" which lubricate the joint to permeate through that membrane. The massive hyaluronate molecules are assumed to not penetrate or permeate through the membranes at all, while the smaller building blocks of cartilage (such as glucosamine and chondroitin) can gradually

permeate through the membranes, allowing them to reach the cartilage beneath the membranes. The exact relationship between the membrane and the different components of the lubricin/SAPL complexes is not yet fully understood; however, for purposes of the following simplified description, it is assumed that the lubricin molecules can either penetrate the collagenous membrane, or at least partially enter that membrane, while the SAPL molecules do not penetrate or enter the membrane at all (at least, not in substantial quantities).

Fig. 26B (labelled "Instantaneous Loading") illustrates what happens when the joint is initially compressed after being at rest, such as when the person stands up. As the person goes through the motion of standing, the bottom surface of the femoral runner begins to slide toward the rear, on the the tibial plateau. As this type of sliding motion occurs, pressure is imposed on the joint, due to the weight of the person.

During this initial sliding and loading motion, within the zone of highest pressure within the joint, the cartilage surfaces on the femur and tibia initially engage in a "hydroplaning" motion. As this is occurring, the macromolecules in the synovial fluid are being compressed, as shown by their slightly greater density in Fig. 26B compared to the fluid in the relaxed joint of Fig. 26A. However, these macromolecules have not yet had time to begin permeating into either of the cartilage membranes, and the much smaller water molecules have had only an instant to commence that process. The two cartilage membranes do not contact each other during this "hydroplaning" stage; instead, the femoral runner is kept suspended above the tibial plateau by the layer of watery synovial fluid between them.

Fig. 26C ("Static Compression") schematically illustrates the condition that will arise within the zone of maximum compression inside the joint, if the person remains standing still for several minutes. Under sustained static pressure, the lubricin/SAPL complexes, which are forced to seek an arrangement that minimizes their volume, begin to line up in an aligned configuration as shown. The lubricin "heads" will, to at least some extent, contribute to this alignment between the cartilage membranes; although this process is not fully understood, it is assumed herein, for purposes of discussion and illustration, that the lubricin heads will fit into the interstitial spaces between adjacent collagen fibers in the cartilage membranes, and the SAPL "tails" project will away from the membrane, into the synovial fluid. In addition, this type of static compression will also tend to drive water molecules (which are much smaller and more mobile) out of the high-pressure zone with

maximal compression, thereby increase the concentration of the remaining lubricant components in that zone, which will increase the thickness and viscosity of the lubricant fluid that remains.

Fig. 26D ("Hydroplaning Motion") illustrates what happens if the person then begins walking forward, after standing still for a sustained period. Shear forces exerted on the synovial fluid by the relative motion of the two membranes cause the SAPL/lubricin concentrate in the contact zone to lubricate the initial launch of the joint into a hydroplaning mode of load transfer. As mentioned above, this type of action may cause at least some of the lubricin/SAPL complexes to be pulled apart or otherwise altered.

These various actions (including possible dissociation of SAPL from lubricin, mixing of the SAPL molecules with hyaluronate, and removal of water and other small solute molecules from the high-pressure zone) lead to formation of a highly viscous, slippery, "slimy" fluid between the two cartilage segments, when the person is standing still. Upon initiation of walking, the surfaces begin a "hydroplaning" interaction relative to each other, and thereby promote the clearing of the surface membranes for future alignment of lubricin/SAPL complexes when the joint is subsequently statically loaded.

Because of its viscous and slimy nature (and, it is hypothesized herein, because free SAPL molecules in the viscous fluid may be attracted to lubricin molecules that have become embedded in the surfaces of the cartilage membranes), the lubricating components of the synovial fluid (mainly hyaluronate and SAPL molecules) continue to keep the two cartilage segments separated from each other, so that the two opposing cartilage segments still do not directly contact each other, even if the person continues to walk or run. This is part of a natural mechanism of fluid cushioning and fluid insulation, which allows cartilage segments in knee and hip joints to remain intact, undamaged, and unabraded, despite all the wear and motion that is imposed on those joints for 70 or 80 years or more, in a healthy person.

Fig. 26E depicts another apparently important factor in a "tribological" analysis of how synovial fluids can manage to lubricate knee and hip joints so successfully (for the most part) for decades. There are 4 semi-circular arrows shown in Fig. 26E. These arrows schematically depict pressures and directional fluid flows, across the two membranes that cover the cartilage segments. These arrows indicate that, in the regions which surround and flank the center of a high-pressure loading zone, water molecules inside the cartilage "gel" (beneath the covering membranes) in each segment of cartilage are being forced out and

away from the central zone where the pressure is highest. These water molecules can flow through the gel, but only slowly, because the fibrous molecular matrix that holds the gel together constrains molecular flow through the gel.

As water molecules in the area of highest pressure inside a knee joint do their best to shift and flow outwardly into the flanking areas, they exert pressure against the surrounding water molecules, which fill the cartilage gel that surrounds the highest pressure region. As indicated by the arrows in Fig. 26E, this type of pressure, acting on small and mobile water molecules that are trapped inside a segment of cartilage gel, causes the semi-permeable membranes which cover the two cartilage segments to be pushed *toward* each other, from beneath, rather than away from each other, in the areas that flank and surround the center zone of highest pressure.

This type of fluid response, by small and semi-mobile water molecules trapped inside a gel structure, causes two important results. The first involves a more even distribution of pressure within a weight-bearing joint, such as a knee joint in a person standing upright. Since the pressures and constrained motions of water inside a cartilage gel cause the surrounding areas of cartilage to press outwardly, away from their bones, those surrounding regions will help support and bear a larger portion of the weight that is being imposed on that knee joint. This type of cooperative assistance, by a roughly ring-shaped circle of cartilage surrounding the center zone of maximum pressure, helps ensure that no single small area of cartilage is forced to bear the entire weight of a person's body. Obviously, this type of pressure-sharing response is important in helping prevent potentially abrasive and destructive direct contact between two opposing segments of cartilage in a knee or hip joint.

The second effect may be equally important, on a long-term basis. The flow of small and mobile water molecules, within the cartilage gel, helps free embedded macromolecules (including lubricin molecules) from the semi-permeable collagenous membrane which covers a cartilage segment. In other words, the motion of water molecules within and through cartilage gel may help "blow out" and rinse out the selectively permeable collagen membrane that covers that segment of cartilage; this can dislodge and remove any lubricin, SAPL, hyaluronate, or other macromolecules that have become embedded in the semi-permeable collagen membrane, and may help clear the membrane for subsequent interactions with fresh lubricin/SAPL complexes. This type of constrained flow of small water molecules through a gel matrix may also help generate and ensure

substantially higher levels of travel and permeation of the nutrient building blocks (including glucosamine and chondroitin) through both the semi-permeable membrane which covers a segment of cartilage gel, and through the cartilage gel itself.

THE "INTER-PENETRATING NETWORK"

Another aspect of natural cartilage is important to understanding the new devices disclosed herein.

In a healthy joint, the outer cartilage surface is NOT bonded to the underlying hard bone by means of a simple planar or curved interface. Instead, the interface between bone and cartilage forms a transition zone, which is several millimeters thick. That transition zone has a "wavy undulating" interface, which can also be described as a set of "interlocking fingers". These undulations (or interlocking fingers) greatly multiply and increase the total area of contact and bonding between soft cartilaginous material, and hard bony material.

Within that zone, the undulating/interlocking interface is heavily traversed by a network of collagen fibers. These microscopic fibers, which are present at a density of thousands of fibers per square inch of interface, are often referred to as the "inter-penetrating network" (IPN). Each microscopic fiber crosses a boundary between cartilage material and bone material. The opposing ends of a fiber do not terminate at the interface; instead, each fiber penetrates into, and is anchored within, the material type that surrounds both of its ends. Accordingly, this dense mesh of IPN fibers greatly reinforces and strengthens the bond between the relatively soft cartilage layer, and the much harder and more rigid bone structure.

With the foregoing as background information on natural physiology, Figure 27 illustrates, in cross-section, a multi-layer synthetic envelope 968 which provides both (i) a semi-permeable outer membrane that remains constantly wet, and (ii) a fibrous supporting network which increases the support for and strength of the outer membrane. Each layer of this envelope 968 is described below, in sequence.

The outermost layer (shown as layer 970 in Fig. 7) is a relatively thin "selectively permeable" membrane, modelled after the outermost membrane of natural cartilage, which is composed mainly of collagen fibers. This membrane should be permeable to water molecules (and possibly certain other components of synovial fluid, depending on other design factors of the complete membrane assembly). It preferably should also promote the

concentration of lubricin/SAPL molecules near the membrane surface, in a manner comparable to the actions of natural cartilage membranes as they interact with lubricin/SAPL molecules during joint motion (this statement is based on the simplifying assumption set forth in the Background section). Alternatively, using hydrophilic synthetic polymers, it may be possible to use chemical or physical crosslinking agents or other techniques to modify the superficial surface layer of a permeable material such as a hydrogel, in a manner which generates a relatively tough and durable selectively permeable surface membrane which can function in a similar manner.

Various types of known polymers can be used to create hydrophilic membranes with pore structures that make them permeable to water. One such compound includes a blend of poly(vinyl alcohol) (abbreviated as PVA) mixed with certain other compounds such as poly(vinyl pyrrolidone) (PVP). As discussed in articles such as Peppas 1987, Nishio et al 1990, Zhang et al 1992, Hickey et al 1995, and Cassu et al 1997 and 1999, membranes made of PVA/PVP blends can be made with a desired range of pore sizes, without using potentially toxic initiators, cross-linkers, or other chemical agents that might leach out of the final product if used during manufacture.

Numerous other biocompatible hydrophilic polymers have been developed for surgically implanted devices, and manufacturing techniques are known for making porous films or other articles from such polymers. In addition, intensive research is constantly being done at universities, medical schools, and private companies, on improved molecular combinations, improved manufacturing techniques, and improved methods of modifying and adapting already-known polymers to new and emerging uses. Accordingly, any such polymer compound which is currently known or hereafter discovered, and which has a proper combination of hydrophilicity, permeability, biocompatibility, non-rigid hardness, and durability, can be evaluated for use as a semi-permeable surface layer on a cartilage replacement implant as disclosed herein, using no more than routine experimentation.

The next layer deeper in the assembly, shown as layer 972 in Fig. 27, can be made of a cushion-type or hydrogel substance. For example, a non-resorbable fiber-reinforced polyurethane material which has been manufactured in a way that causes it to be porous and hydrophilic, and which has an elastic modulus of about 20 MPa, offers a promising candidate for such use. If a hydrogel-type material is being developed for use as disclosed herein, any of several types of hydrophilic synthetic polymers (for example, using chemistry involving polyethylene terephthalate, polyvinyl alcohol, or a hydroxy-acrylate

compound) offer promising candidates for evaluation.

It also should be noted that the network of fibers 974 embedded in layer 978 and membrane 976 will extend partially into layer 972, for additional reinforcement and strength.

The next deeper layer in the assembly, shown as membrane 976 in Fig. 27, is a boundary or transition layer which separates the cushion/hydrogel layer 972 from the underlying layer 978. The construction and design of membrane 976 will depend on several factors, including (i) whether it must support a cushion layer or a hydrogel layer in zone 972, and (ii) what type of structure it will sit on top of, in layer 978.

In the configuration shown in Fig. 27, membrane 976 rests on top of layer 978 which contains a network of fibers that are modelled after the IPN network of collagen fibers found between a cartilage segment and the underlying bone in a natural joint. These fibers can be made from any suitably strong material; even though they will be sealed inside an envelope and will not normally be contacted by biological fluids, they nevertheless should be made of a biocompatible material, since a risk of rupture, leakage, or other unforeseen problem is always present, especially in a joint that is subject to relatively large pressures and weight loads. Any suitably strong biocompatible material may be used; as one example, polyethylene therephthalate fibers offer a promising candidate for such use.

Layer 978 may be filled, after surgical implantation of the empty envelope 968, with a fluid pre-polymeric compound that will set and solidify into a polymer having the desired traits; alternately, it may be possible to fill the envelope that creates layer 978 with a fluid compound that does not set and solidify. In general, layer 978 functions in a manner that is modelled after the "wavy undulating" or "interlocking fingers" transition zone that exists between hard bone and soft cartilage in a native joint.

In one type of design, which can be used in a non-resorbable synthetic implant, layer 978 can be composed of a single molded piece of semi-flexible resilient material, with an appropriate level of stiffness that will provide a gradated transition between the relatively soft cushion or hydrogel in layer B, and the much harder rigid structure of the underlying bone.

In a second type of design, layer 978 can be a fluid-filled, polymer-filled, or comparable layer that also contains a network of fibers, as illustrated in Fig. 978, which connect to (and possibly extend through) membrane 976, pass through layer 978, and connect to bone-anchoring membrane 980.

Depending on various factors (including the spacing, diameter, and density of the fibers, the viscosity of the fluid within layer 978, etc.), a layer 978 which is provided with an IPN reinforcing system can be designed to ensure that membrane 976 will behave in a desired manner in response to any type of pressure and fluid flow that arises within layer 972. In addition, a fibrous IPN system inside layer 978 can also help guard against distortion of the implant; for example, it may allow layer 978 to be filled under pressure, to ensure that it takes the exact desired shape without risk of overfilling and distortion.

In a third type of design, layer 978 can be filled with a rigid or semi-rigid polymer with selected physical characteristics that are similar to the traits of bone, such as polymethylmethacrylate (PMMA), which can be fiber-reinforced for added strength.

The bone-anchoring membrane, designated as layer 980 in Fig. 27, is designed to be rigid and non-flexible, so that it can be anchored directly and permanently to a surgically-prepared hard bone surface 986. In one approach, pin-type anchors and a suitable cement 982 (such as a polymethyl-methacrylate) can be used. These can be supplemented, if desired, by trenches 984 or other non-planar preparation of bone surface 986, as illustrated in Fig. 27, to ensure permanent and non-movable anchoring of membrane 980 to the bone surface. Alternately, a mesh or screen can be used in membrane 980, coated with a calcium-phosphate material to mimic the apatite structure of bone if desired, to ensure permanent anchoring of the implant assembly by promoting bony ingrowth into a porous structure.

One of the attractions and potential advantages of using the IPN approach to designing layer 978, and of using a hydrogel rather than a cushion for layer 972, is that these design approaches will allow easier arthroscopic insertion of a large membrane assembly, in collapsed unfilled form, into a joint, through insertion tubes that are roughly the diameter of a finger or thumb.

PACKAGED ARTICLE OF MANUFACTURE

Certain claims refer to an article of manufacture, comprising a sealed package containing a sterile flexible device as disclosed herein. An illustration of such a package is provided in Fig. 18. In this depiction, a vacuum-sealed plastic package 990 comprises bottom layer 992 and top layer 994, sealed to each other by a heat-sealed peripheral seal 996 (one corner of the top layer is shown lifted, solely for illustrative purposes). Enclosed within this sealed plastic package is an arthroscopic insertion tube 997, which contains a

rolled-up scaffold envelope 998 inside the tube. A fluid inlet tube 999 extends out of one end of tube 997. This type of tube can be used to help a surgeon insert a tightly-compressed rubbery device through a small skin incision. Once the advancing tip of the tube has approached its intended location, the rolled-up scaffold is pushed out of the tube, with the aid of a blunt rod, plunger, or other suitable device. The surgeon then carefully works the scaffold into position, ensuring that it does not tear the skin incision or other vulnerable tissue as it returns to its molded shape.

Thus, there has been shown and described a new and useful means for using inflatable scaffold envelopes to replace segments of damaged cartilage in mammalian joints. Although this invention has been exemplified for purposes of illustration and description by reference to certain specific embodiments, it will be apparent to those skilled in the art that various modifications, alterations, and equivalents of the illustrated examples are possible. Any such changes which derive directly from the teachings herein, and which do not depart from the spirit and scope of the invention, are deemed to be covered by this invention.

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CLAIMS

1. A surgically implantable device for replacing a segment of damaged cartilage in a mammalian joint, comprising a flexible envelope suitable for surgical implantation in a joint, wherein the flexible envelope:

(i) is designed to be flexed into a shape that allows it to be surgically inserted into a joint having damaged cartilage, using arthroscopic tools and methods;

(ii) can be restored to a desired size and shape which is useful for replacing a segment of damaged cartilage, after the flexible envelope has been inserted into the joint through a skin incision;

(iii) is designed to be permanently anchored to a bone surface;

(iv) has a fluid inlet orifice which allows the flexible envelope to be filled, after it has been surgically inserted into a joint, with a fluidized compound that will set into a solidified material inside the flexible envelope, thereby creating a filled implant consisting essentially of an envelope and the material contained within the envelope,

wherein the flexible envelope is suited in all respects for use in such manner, and thereby enables a surgeon to create inside a joint, using arthroscopic methods, a filled implant which is permanently anchored to a bone surface and is medically effective in replacing a damaged segment of cartilage.

2. The surgically implantable device of Claim 1, which is made of a flexible synthetic polymer that is biocompatible, non-immunogenic, and not degraded or resorbed by bodily fluids.

3. The surgically implantable device of Claim 1, which has an internal surface capable of forming a strong permanent bond with a cold-setting polymeric mixture used for insertion into the flexible envelope during an arthroscopic procedure.

4. The surgically implantable device of Claim 1, which has a shape and size designed to replace a cartilage segment in a knee joint selected from the group consisting of a medial femoral condyle and a lateral femoral condyle.

5. The surgically implantable device of Claim 1, which has a shape and size designed to replace an entire femoral cartilage surface which includes a medial femoral condyle, a lateral femoral condyle, and a femoral portion of a patello-femoral compartment.

6. The surgically implantable device of Claim 1, which has a shape and size designed to replace a cartilage segment in a knee joint selected from the group consisting of a medial tibial plateau and a lateral tibial plateau.

7. The surgically implantable device of Claim 1, which has a shape and size designed to replace a cartilage segment in a knee joint which includes both a medial tibial plateau and a lateral tibial plateau.

8. The surgically implantable device of Claim 1, which has a shape and size designed to replace a patello-femoral cartilage segment in a knee joint.

9. The surgically implantable device of Claim 1, which has a shape and size designed to replace a cartilage segment in a ball-and-socket joint.

10. The surgically implantable device of Claim 1, which has an articulating surface made of a porous hydrophilic material.

11. A method of surgically replacing a segment of damaged cartilage in a mammalian joint, comprising the following steps:

(a) preparing a cartilage-bearing surface of a bone in a joint that has suffered damage to the cartilage, so that said surface is ready to receive a surgical implant that can replace the damaged cartilage;

(b) inserting into the joint a deformable envelope;

(c) positioning the deformable envelope over the surface of the bone which has been prepared as provided in step (a);

(d) permanently anchoring the deformable envelope to the surface of the bone, and filling the deformable envelope with a fluidized compound that will set into a solidified material inside the envelope, resembling natural cartilage,

wherein the steps listed above generate a filled implant consisting essentially of the

flexible envelope and the material inside the envelope, wherein the filled implant is permanently anchored to a bone surface and is medically effective in replacing a damaged segment of cartilage.

12. The method of Claim 11, wherein the deformable envelope is made of a flexible synthetic polymer that is biocompatible, non-immunogenic, and not degraded or resorbed by bodily fluids.

13. The method of Claim 11, wherein the deformable envelope has an internal surface capable of forming a strong permanent bond with a cold-setting polymeric mixture used for insertion into the flexible envelope during an arthroscopic procedure.

14. The method of Claim 11, wherein the deformable envelope has a shape and size designed to replace a cartilage segment in a knee joint selected from the group consisting of a medial femoral condyle and a lateral femoral condyle.

15. The method of Claim 11, wherein the deformable envelope has a shape and size designed to replace an entire femoral cartilage surface which includes a medial femoral condyle, a lateral femoral condyle, and a femoral portion of a patello-femoral compartment.

16. The method of Claim 11, wherein the deformable envelope has a shape and size designed to replace a cartilage segment in a knee joint selected from the group consisting of a medial tibial plateau and a lateral tibial plateau.

17. The method of Claim 11, wherein the deformable envelope has a shape and size designed to replace a cartilage segment in a knee joint which includes both a medial tibial plateau and a lateral tibial plateau.

18. The method of Claim 11, wherein the deformable envelope has a shape and size designed to replace a patello-femoral cartilage segment in a knee joint.

19. The method of Claim 11, wherein the deformable envelope has a shape and size designed to replace a cartilage segment in a ball-and-socket joint.

20. The method of Claim 11, wherein the deformable envelope has an articulating surface made of a porous hydrophilic material.

21. An article of manufacture comprising a sealed package containing a sterile flexible device for replacing a segment of damaged cartilage in a mammalian joint, wherein the sterile flexible device:

(i) is sufficiently flexible to allow it to be arthroscopically inserted into a damaged joint;

(ii) can be restored to a desired size and shape inserted into the damaged joint;

(iii) is designed to be permanently anchored to a bone surface; and

(iv) is designed to be filled with a fluidized compound that will set into a solidified material, thereby generating a filled implant consisting of the flexible device and the material inside the flexible device, wherein the filled implant is permanently anchored to a bone surface and is medically effective in replacing a damaged segment of cartilage.

22. The article of manufacture of Claim 21, wherein the flexible device is made of a synthetic polymer that is biocompatible, non-immunogenic, and not degraded or resorbed by bodily fluids.

23. The article of manufacture of Claim 21, wherein the flexible device has an internal surface capable of forming a strong permanent bond with a cold-setting polymeric mixture used for insertion into the flexible envelope during an arthroscopic procedure.

24. The article of manufacture of Claim 21, wherein the flexible device has a shape and size designed to replace a cartilage segment in a knee joint selected from the group consisting of a medial femoral condyle and a lateral femoral condyle.

25. The article of manufacture of Claim 21, wherein the flexible device has a shape and size designed to replace an entire femoral cartilage surface which includes a medial femoral condyle, a lateral femoral condyle, and a femoral portion of a patello-femoral compartment.

26. The article of manufacture of Claim 21, wherein the flexible device has a shape and size designed to replace a cartilage segment in a knee joint selected from the group consisting of a medial tibial plateau and a lateral tibial plateau.

27. The article of manufacture of Claim 21, wherein the flexible device has a shape and size designed to replace a cartilage segment in a knee joint which includes both a medial tibial plateau and a lateral tibial plateau.

28. The article of manufacture of Claim 21, wherein the flexible device has a shape and size designed to replace a patello-femoral cartilage segment in a knee joint.

29. The article of manufacture of Claim 21, wherein the flexible device has a shape and size designed to replace a cartilage segment in a ball-and-socket joint.

30. The article of manufacture of Claim 21, wherein the flexible device has an articulating surface made of a porous hydrophilic material.

31. A surgically implantable device for use in repairing a damaged mammalian joint, comprising:

(i) a flexible outer rim having an anchoring edge and an articulating edge, which is designed to be flexed into a shape that allows it to be surgically inserted into a damaged joint through a minimally invasive incision, using arthroscopic tools and methods, and which can be restored to its manufactured size and shape after it has been inserted into the damaged joint through a skin incision; and,

(ii) a plurality of anchoring components at spaced locations around the outer rim, designed for use with anchoring pins or staples to permanently secure the outer rim to a prepared bone surface in the damaged joint,

wherein the device is made of a biocompatible polymer that is suitable for surgical emplacement inside a joint, and wherein the outer rim has a diameter and height which allow the device to be surgically implanted in a damaged mammalian joint on a prepared bone surface that is normally covered by cartilage, in a manner which assists a surgeon in preparing and anchoring to the prepared bone surface a synthetic device or material which is medically effective in replacing a damaged segment of cartilage.

32. The surgically implantable device of Claim 31, wherein the anchoring edge of the outer rim has a larger diameter than the articulating edge of the outer rim, thereby imparting a sloped angle to the outer rim when the outer rim is placed on a flat surface.

33. The surgically implantable device of Claim 31, wherein the device has a plurality of visible markings, to serve as location guides during an arthroscopic procedure.

34. The surgically implantable device of Claim 31, wherein the device has an articulating surface made of a porous hydrophilic material.

35. An alignment assembly for assisting arthroscopic or surgical repair of a knee joint in a mammalian patient in need of such repair, comprising:

a. a transverse femoral pin with two opposed ends, which is designed to be driven sideways through a femur bone, and which is suited for supporting a femoral hinge at each of the two opposed ends of the pin;

b. two cammed femoral hinges which are designed to be rigidly mounted on the two opposed ends of the transverse femoral pin;

c. two rigid struts, comprising a medial strut designed for placement on the inner side of the patient's leg, and a lateral strut designed for placement on the outside of the patient's leg, wherein each strut is coupled in a rotatable manner to a cammed femoral hinge;

d. means for securely coupling the two rigid struts to the patient's tibia bone in a non-extendible and non-compressible manner, during an arthroscopic or surgical procedure,

and wherein the two cammed femoral hinges acting in conjunction with the two rigid struts force the tibial bone to move in a cammed travel pathway as the patient's knee is flexed or extended, wherein the cammed path that is travelled by the tibia bone throughout flexion or extension during the arthroscopic or surgical procedure closely resembles the natural cammed travel pathway of the patient's tibia bone during normal flexion or extension of the knee prior to the arthroscopic or surgical procedure.

36. The alignment assembly of Claim 35, wherein the means for securely coupling the two rigid struts to the patient's tibia bone in a non-extendible and non-compressible manner

during an arthroscopic or surgical procedure comprise coupling the two rigid struts to opposed ends of a transverse pin that is designed to be driven through the tibia bone.

37. The alignment assembly of Claim 35, wherein the means for securely coupling the two rigid struts to the patient's tibia bone in a non-extendible and non-compressible manner during an arthroscopic or surgical procedure comprise coupling the two rigid struts to an additional component that is rigidly affixed to the tibia bone by means of at least one bone-penetrating pin.

38. The alignment assembly of Claim 37, wherein the additional component comprises a device which is positioned anterior to the tibia, to assist a surgeon during the arthroscopic or surgical procedure.

39. The alignment assembly of Claim 37, wherein the device comprises a platform component which is provided with at least one coupling means to allow a tool guide to be detachably mounted on the platform component during an arthroscopic or surgical procedure.

40. The alignment assembly of Claim 35 which is designed to be affixed to a patient's leg while the patient's knee is fully extended, thereby establishing fixed and non-varying positioning of the femoral hinges and tibial hinges with respect to each other, while the knee is fully extended.

41. The alignment assembly of Claim 35, wherein at least two tibial pins are affixed to the tibia at different positions on the tibia, in a manner which ensures that the tibia bone cannot rotate relative to either tibial pin.

42. The alignment assembly of Claim 35, wherein at least one second femoral pin is used to ensure that the cammed femoral hinges cannot rotate with respect to the femur.

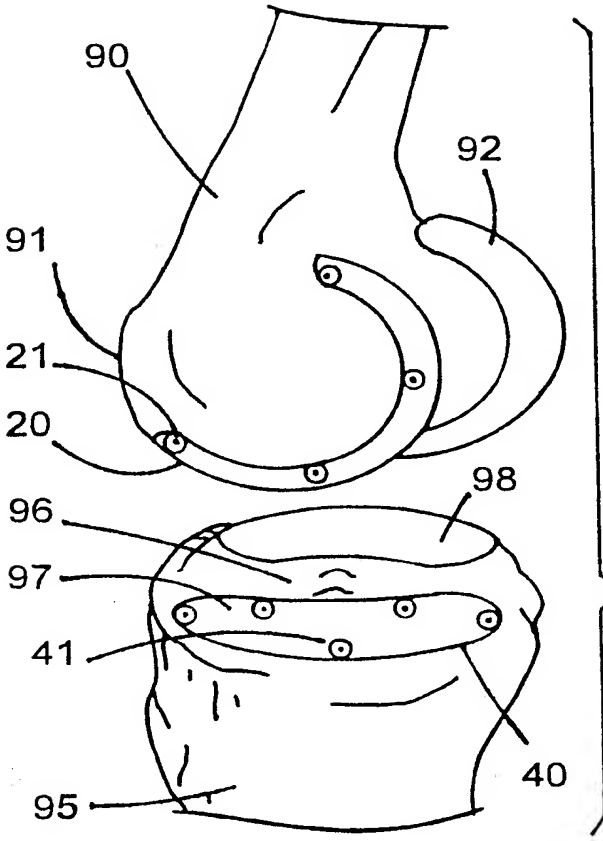

Fig. 1

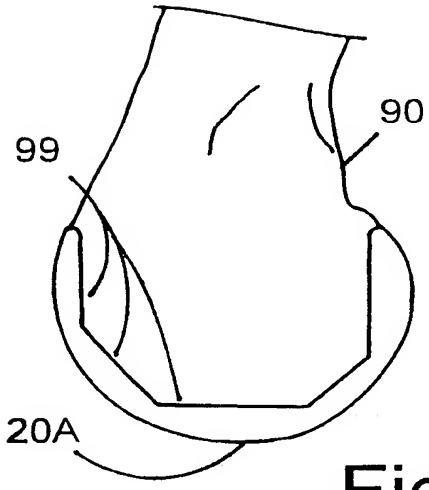

Fig. 3

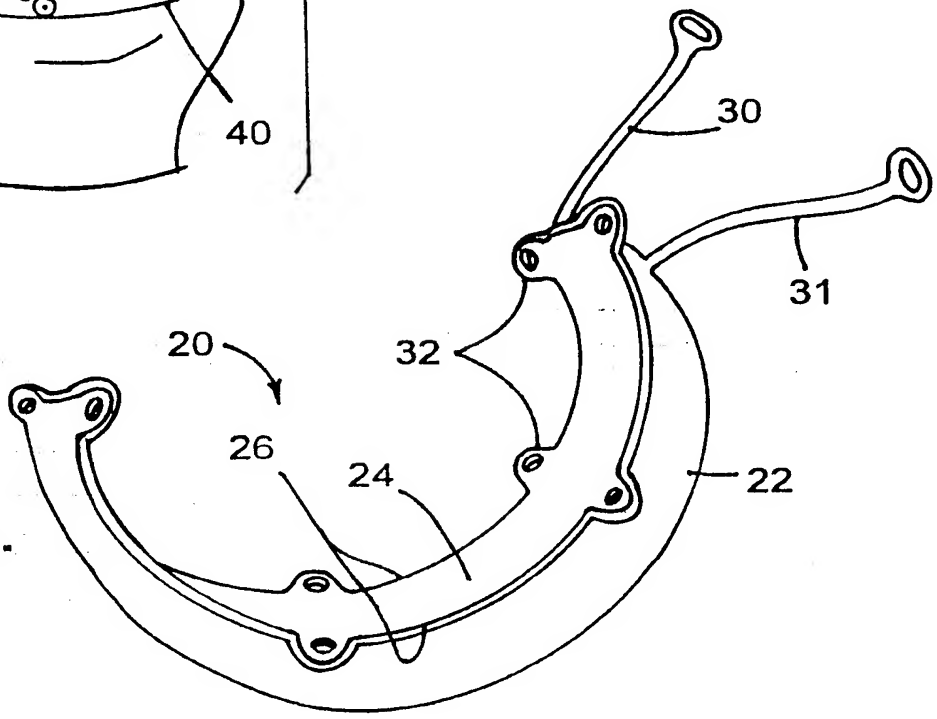

Fig. 2

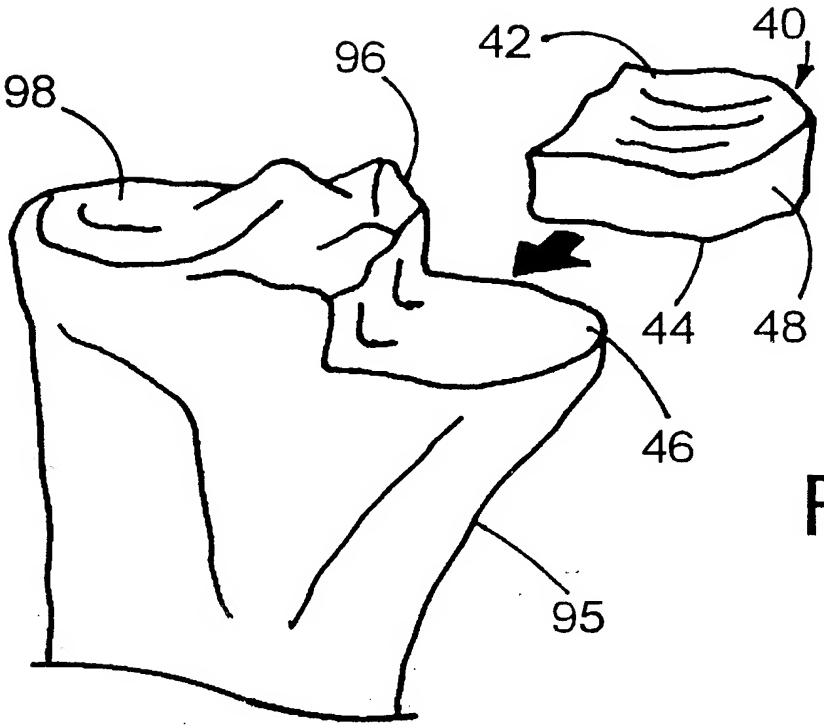
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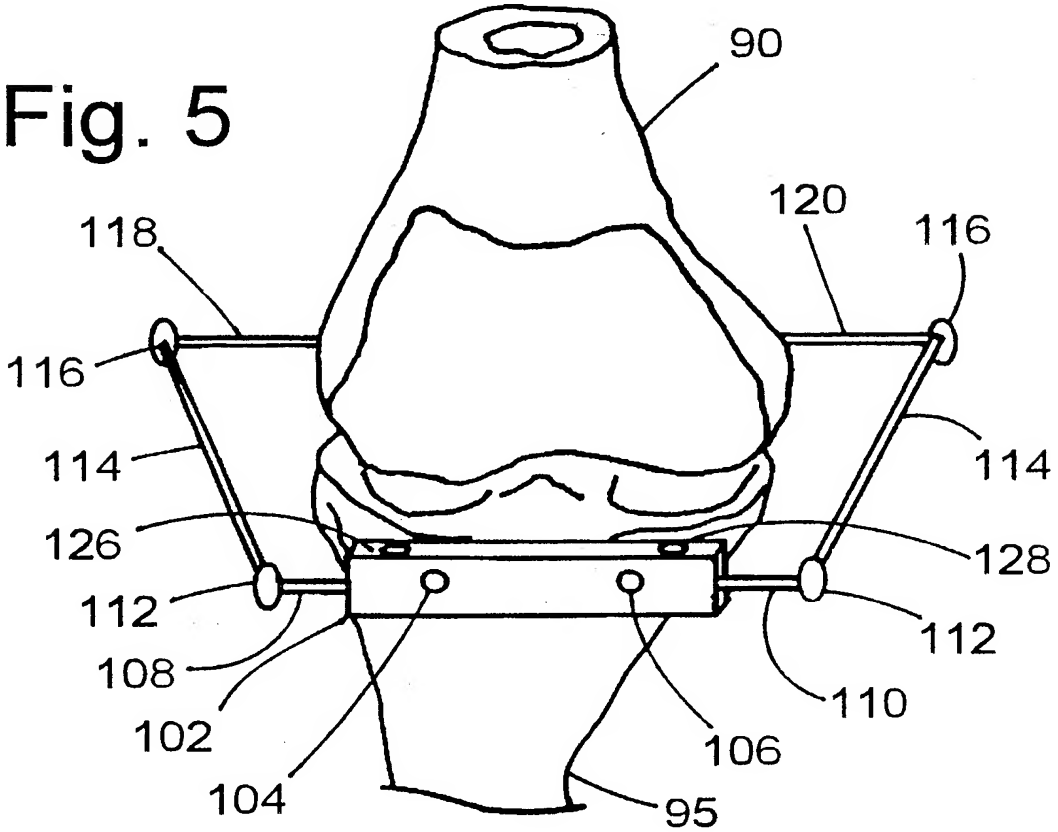
Fig. 4

Fig. 5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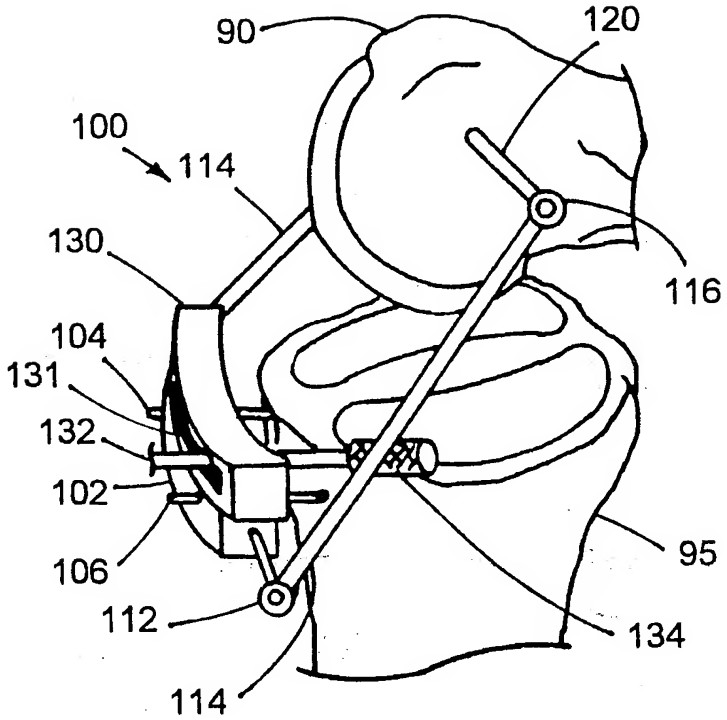
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Fig. 6

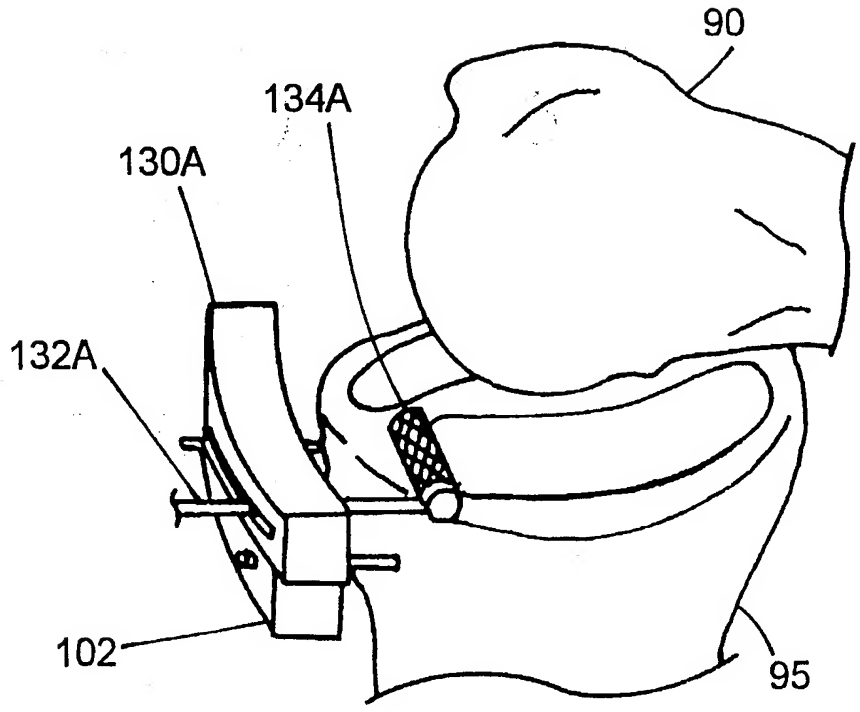
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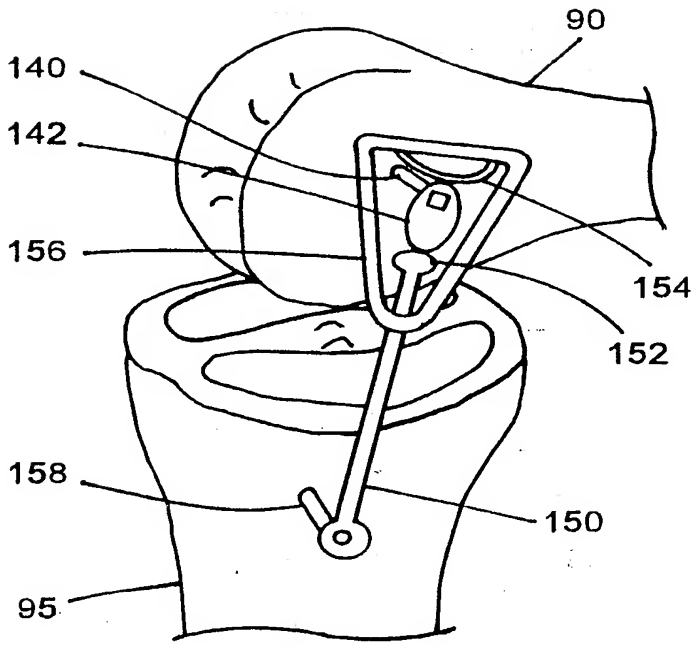
Fig. 7



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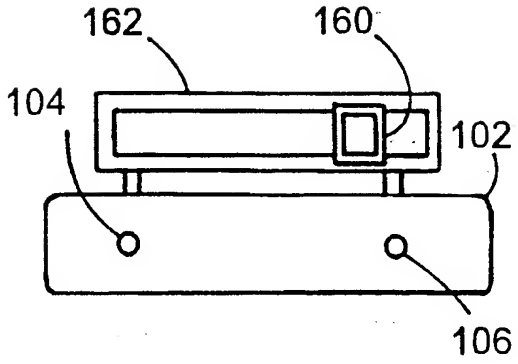


Fig. 9

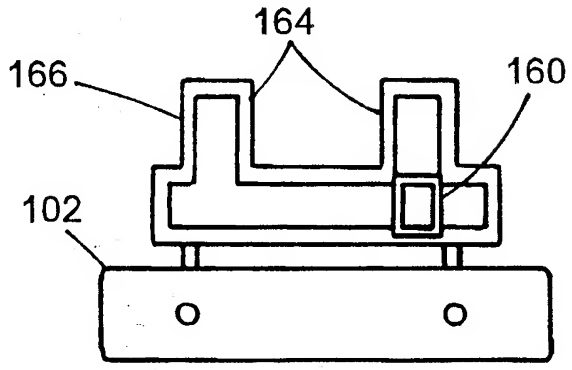


Fig. 10

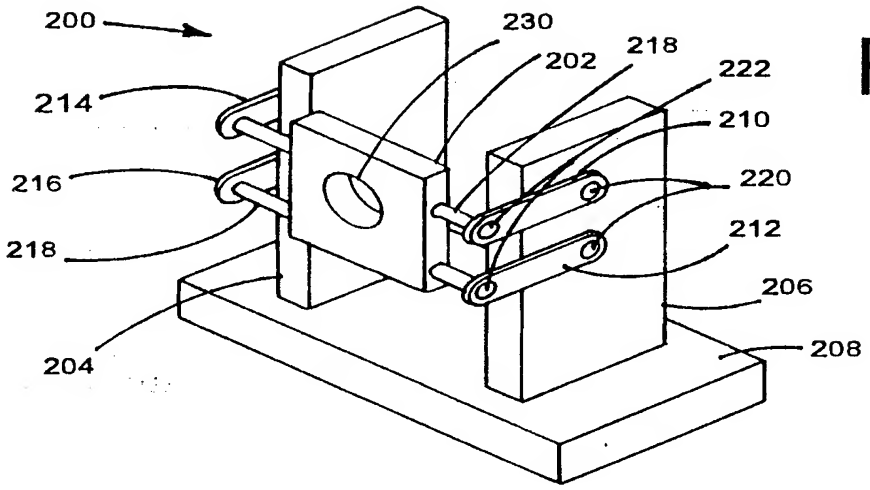
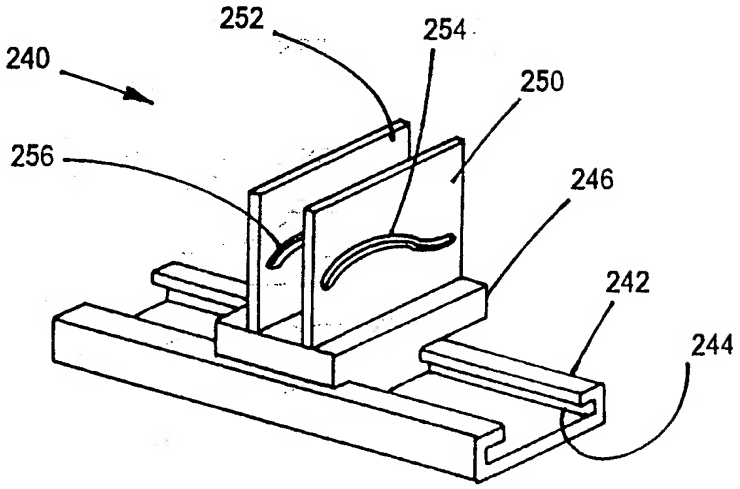


Fig. 11



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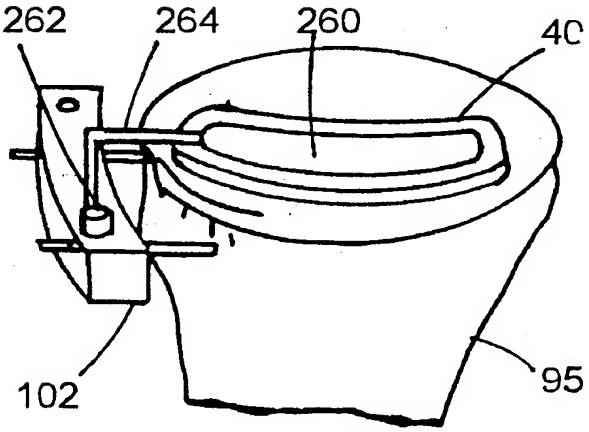

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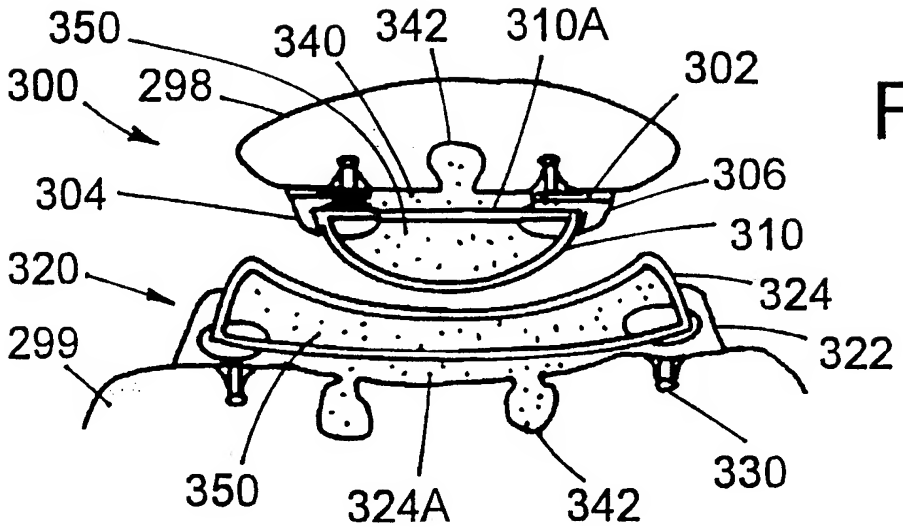
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Fig. 14

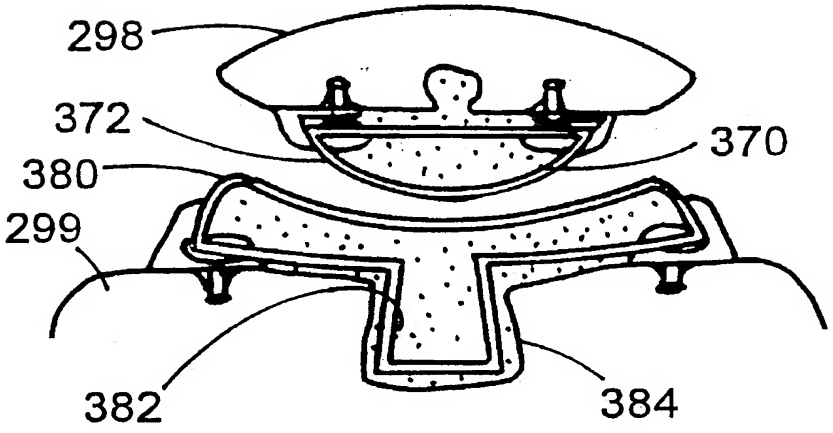
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Fig. 15

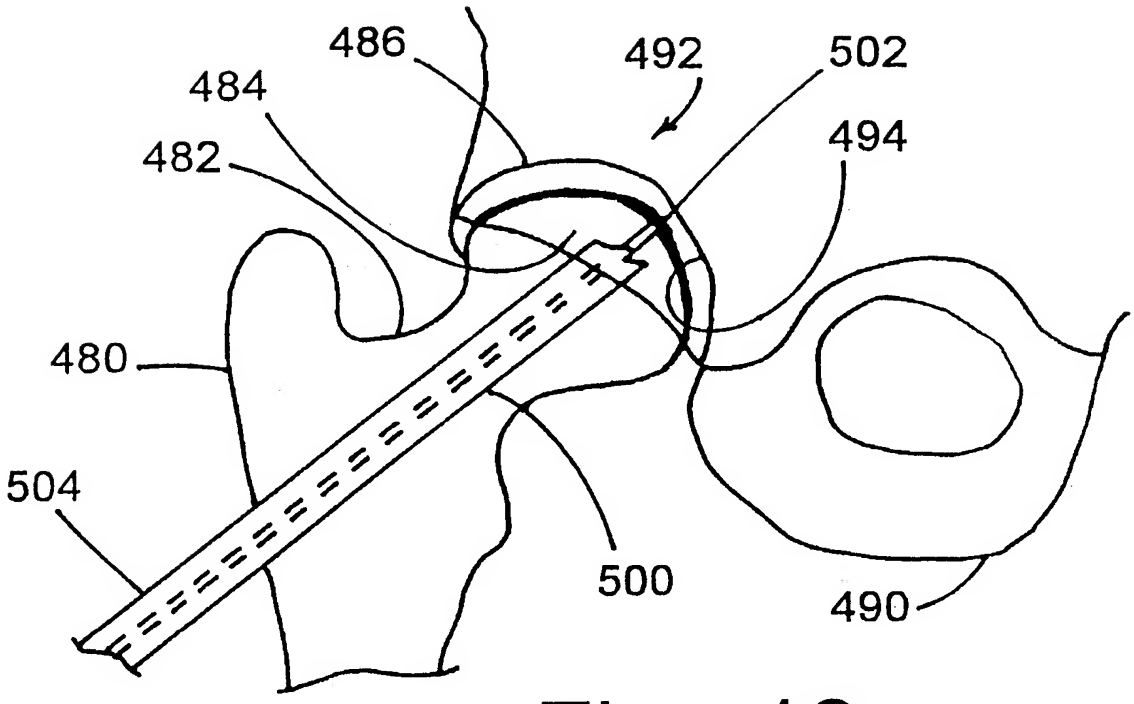
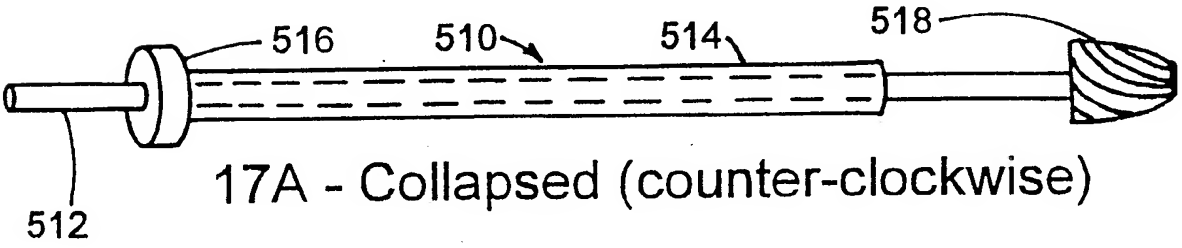
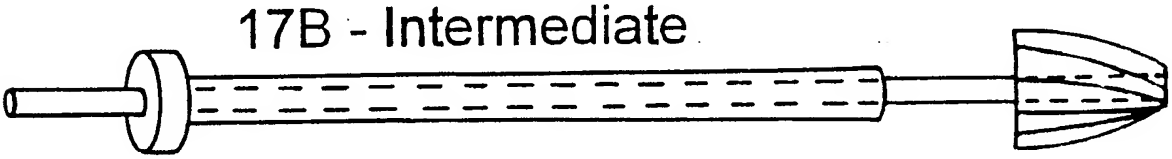


Fig. 16



17A - Collapsed (counter-clockwise)

17B - Intermediate



17C - Extended (clockwise)

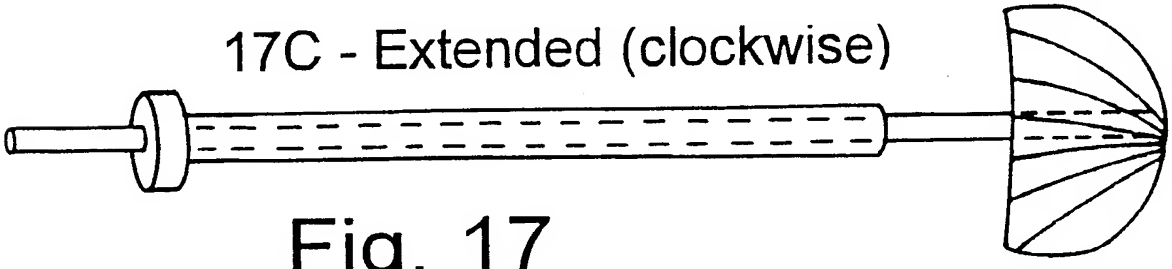


Fig. 17

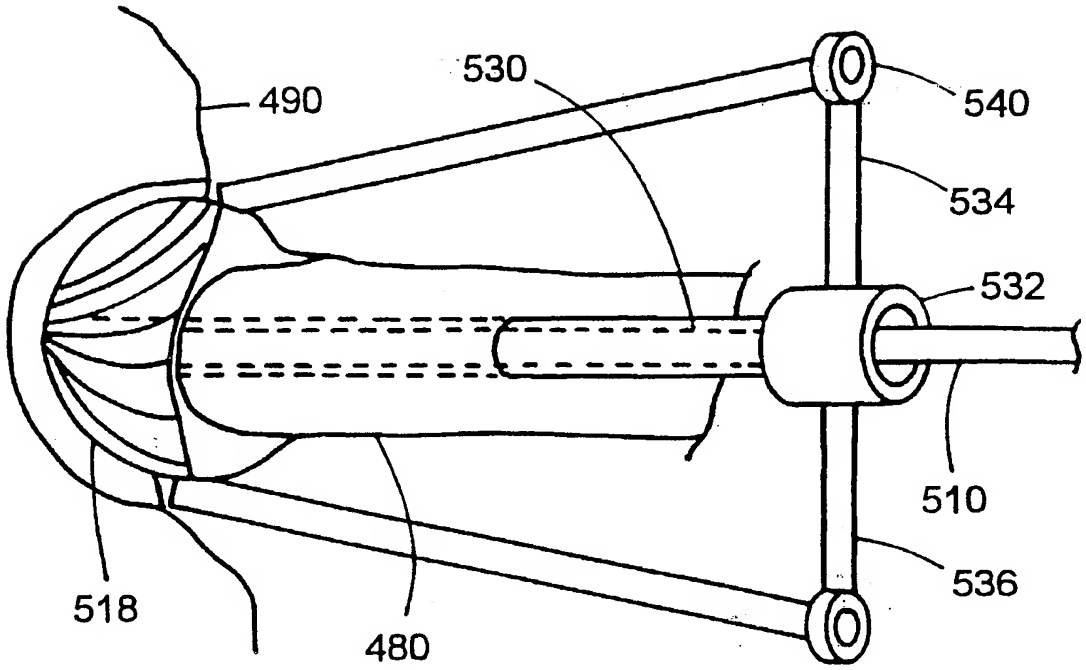

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Fig. 18

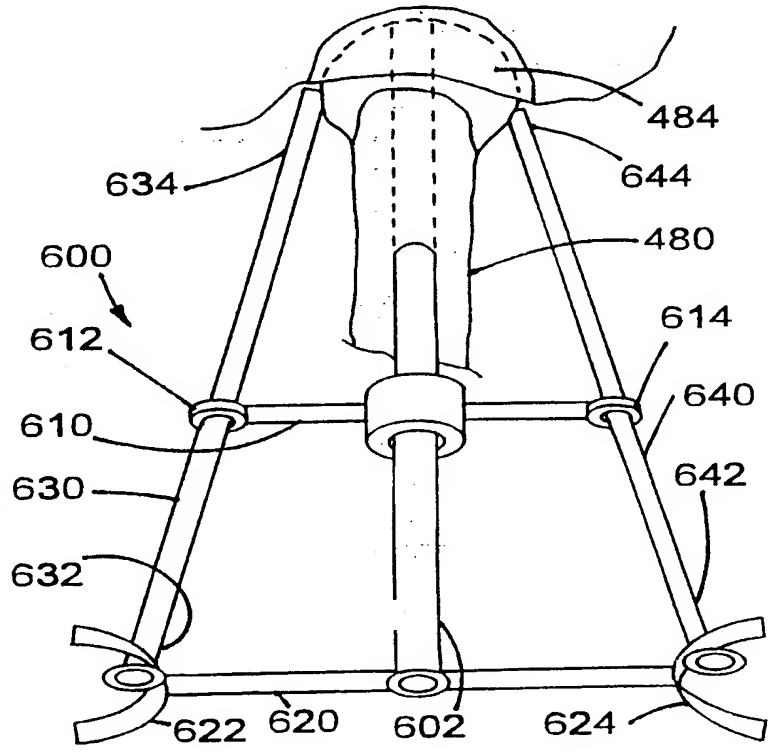
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Fig. 19

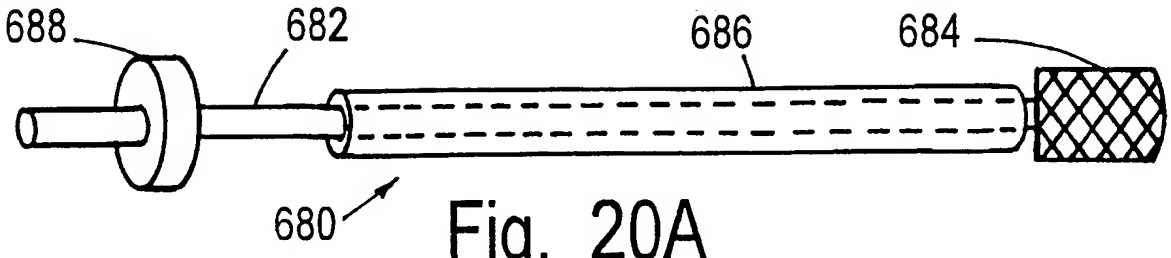

Fig. 20A

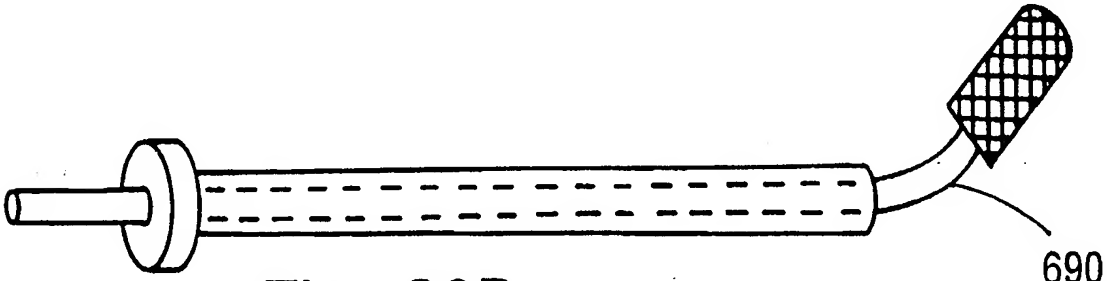

Fig. 20B

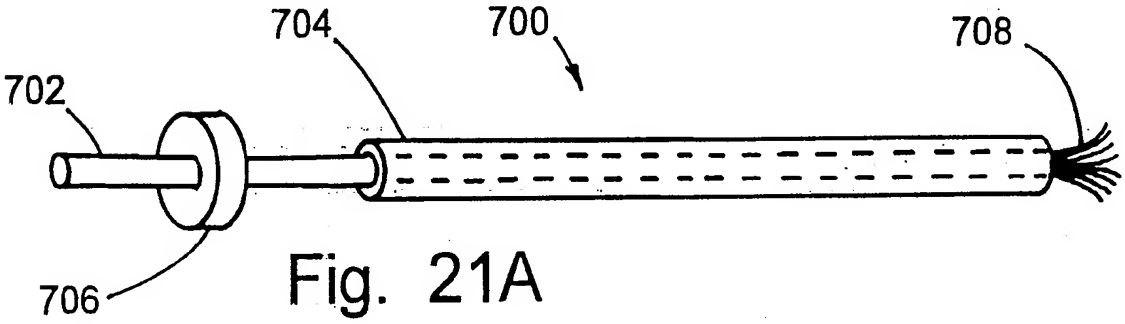

Fig. 21A

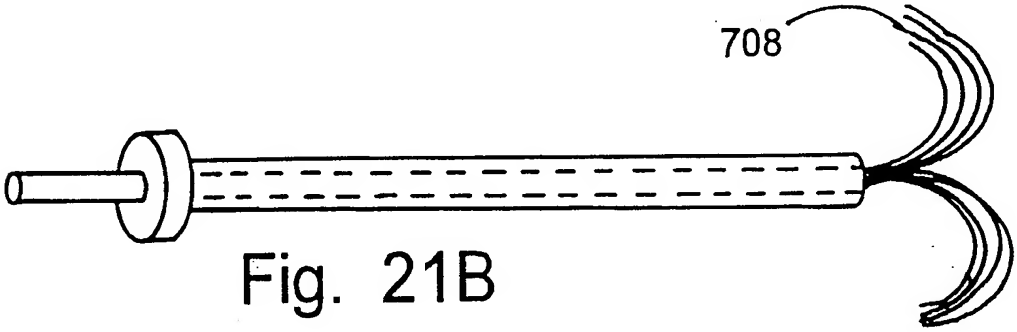

Fig. 21B

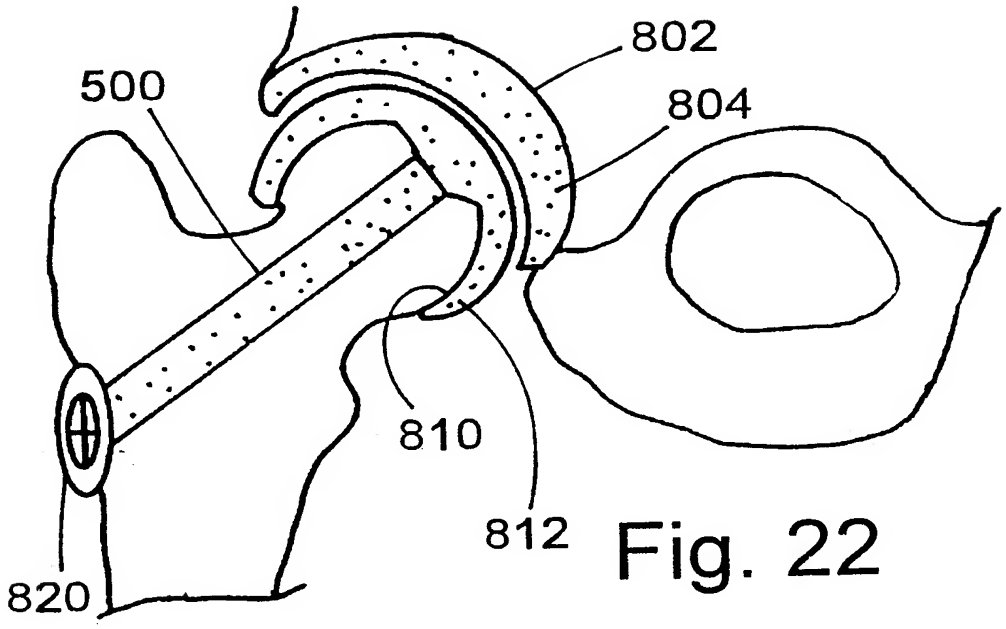

Fig. 22

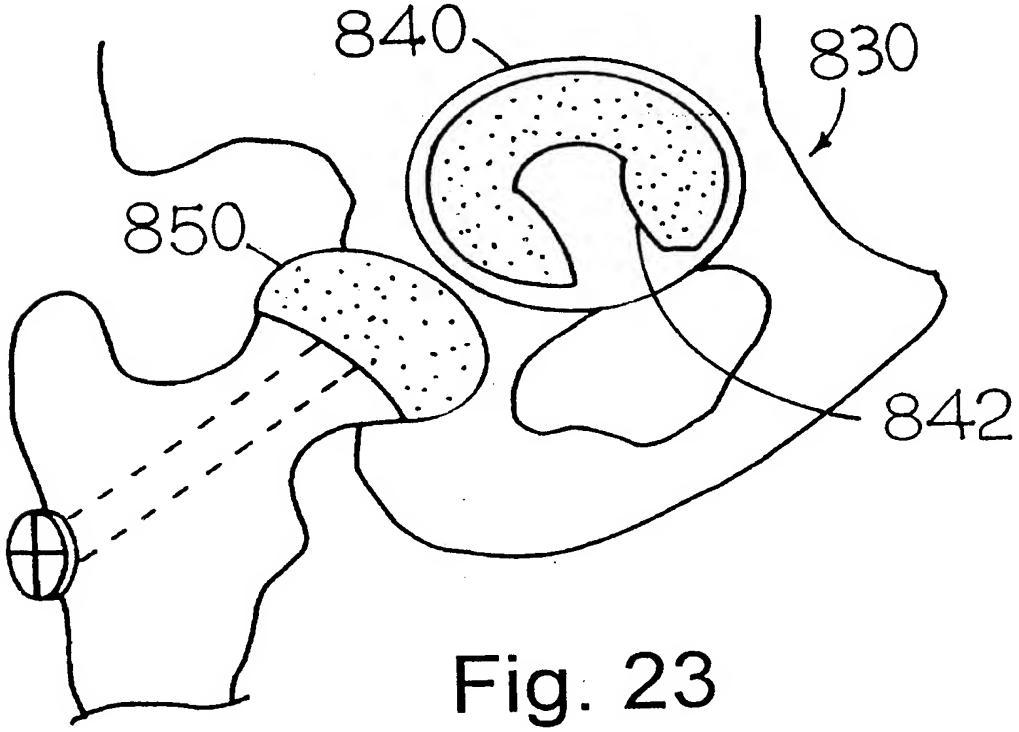

Fig. 23

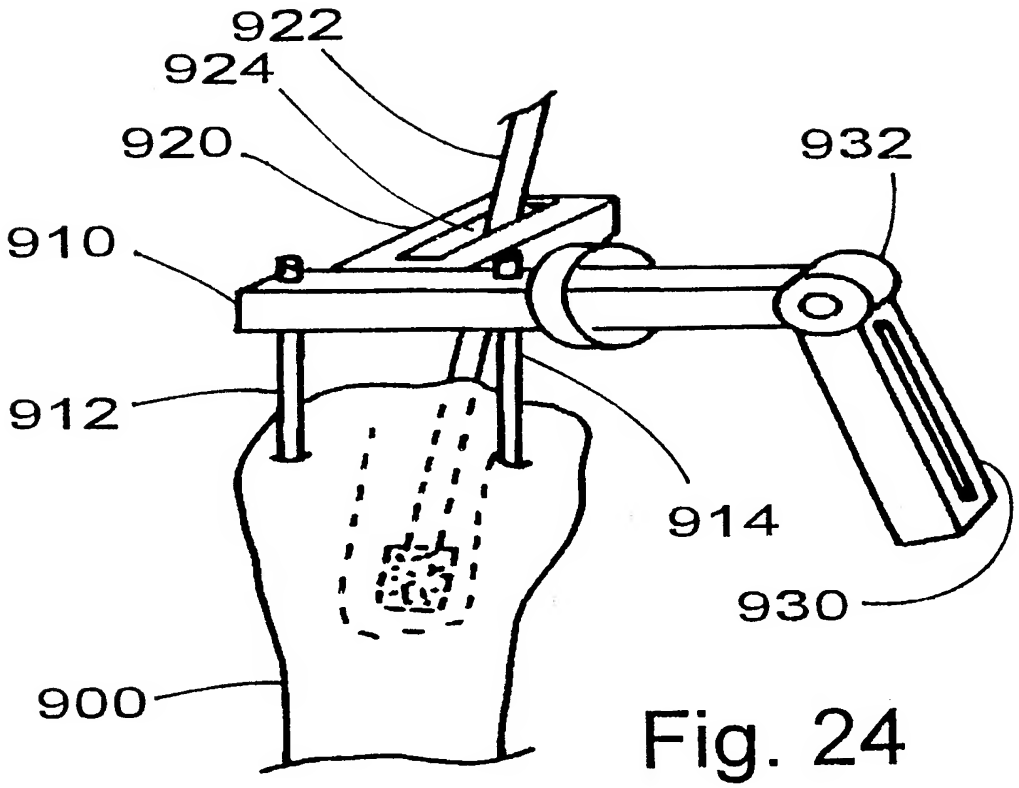

Fig. 24

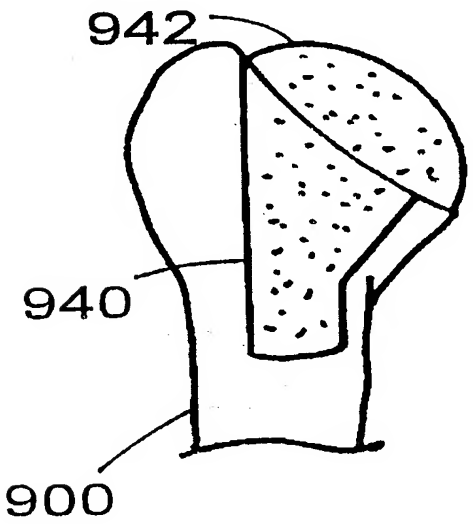

Fig. 25

LEGEND:

- SAPL
- Lubricen
- Lubricen/SAPL complexes
- Hyaluronic acid
- Other macromolecules
- Semi-permeable membranes

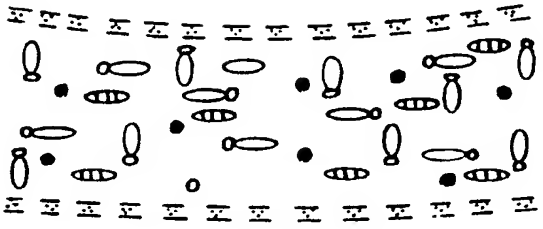

Fig. 26A
UNLOADED JOINT SPACE

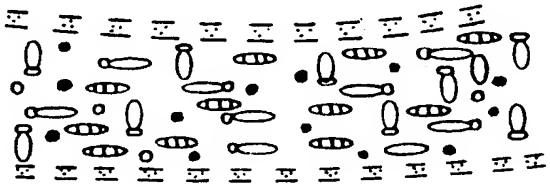

Fig. 26B
INSTANTANEOUS LOADING

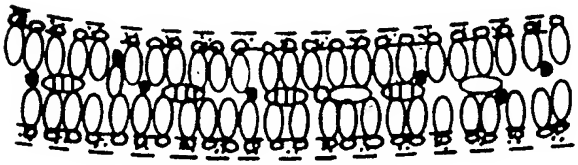

Fig. 26C
STATIC COMPRESSION

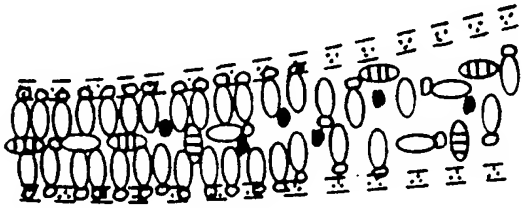

Fig. 26D
HYDROPLANING MOTION

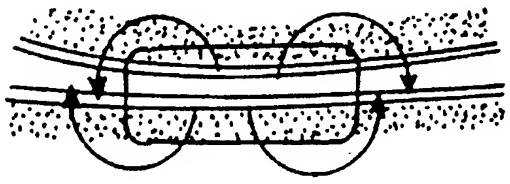

Fig. 26E
LOADED FLUID FLOW THROUGH SELECTIVELY PERMEABLE MEMBRANES

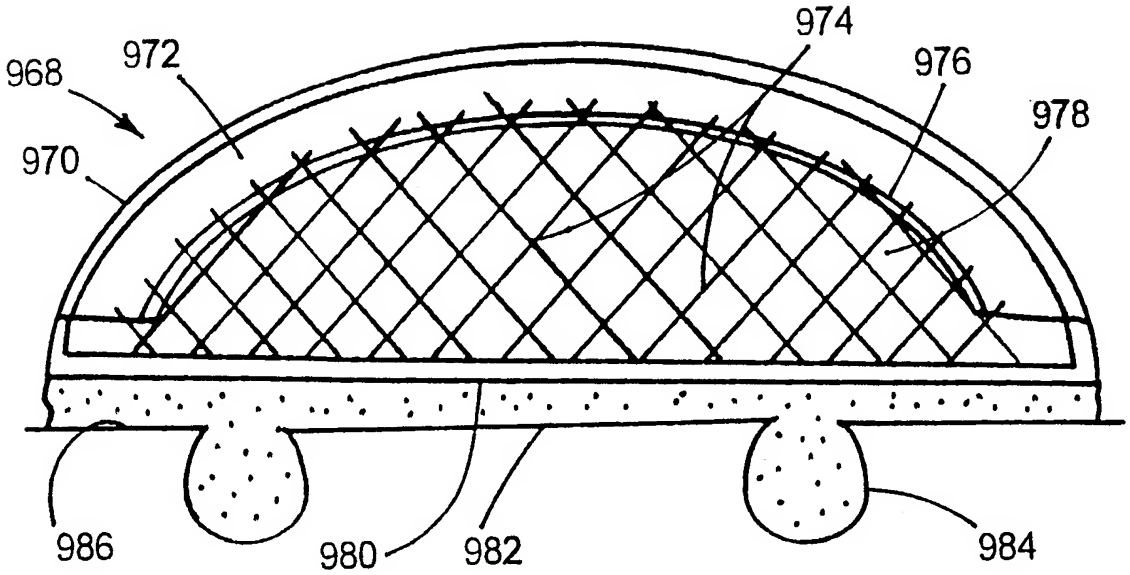
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Fig. 27

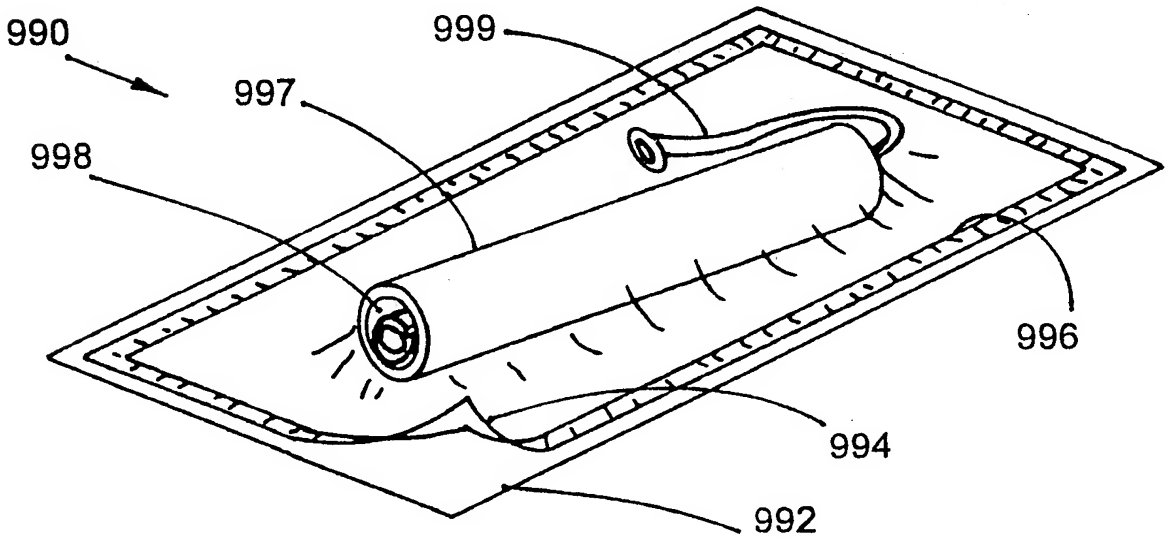
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Fig. 28

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/20492

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61F 2/38
US CL :623/20

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 623/8, 11, 13, 16, 17, 20, 22

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WEST
Search Terms: cartilage, replacement, knee, joint, envelope, curable, bone, surface, flexible

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,556,429 A (FELT) 17 September 1996, entire document.	1-33
A	US 5,358,525 A (FOX et al) 25 October 1994, entire document.	1-33
X --- Y	US 5,344,459 A (SWARTZ) 06 September 1994, Figs. 1-13, col. 3 lines 53-62, and col. 4 lines 17-23.	1-29 --- 30-33
A	US 5,067,964 A (RICHMOND et al) 26 November 1991, entire document.	1-33
A	US 5,007,940 A (BERG) 16 April 1991, entire document.	1-33

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

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05 NOVEMBER 1999	10 DEC 1999
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer TRAM A. NGUYEN Telephone No. (703) 308-0804

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INTERNATIONAL SEARCH REPORT

International application No.
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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4,919,667 A (RICHMOND) 24 April 1990, Fig. 2 element (10).	1-33
A	US 4,344,193 A (KENNY) 17 August 1982, Fig. 1 element (13).	1-33
A	US 4,052,753 A (DEDO) 11 October 1977, Fig. 5 element (68).	1-33
A	US 3,875,595 A (FRONING) 08 April 1975, entire document.	1-33